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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No.	: 10/680,602	Confirmation No. 5764
Applicant	: Olin Palmer et al.	
Filing Date	: October 6, 2003	
Title	: INTRAVASCULAR DEVICE AND SYSTEM	
Art Unit	: 3734	
Examiner	: Kevin Thao Truong	
Docket No.:	: ACS 65628 (G2929USD1)	
Customer No.	: 24201	May 20, 2009

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Dear Sir:

This Appeal Brief is being filed along with a second Notice of Appeal. A first Notice of Appeal was filed on January 11, 2008 in conjunction with the prosecution of this case. Previously, Appellant appealed the final Office Action dated September 11, 2007. A Notice of Panel Decision of Pre-Appeal Review was issued on December 13, 2008, some eleven (11) months after Appellant submitted its Pre-Appeal Brief. The Decision of the Panel was to reopen prosecution. On February 20, 2009, a final Office Action issued which maintained virtually the same rejections raised in the final Office Action dated September 11, 2007.

This second Notice of Appeal and Appeal Brief are being filed within three (3) month of the final Office Action dated February 20, 2009. This second Notice

of Appeal and Appeal Brief are being submitted pursuant to MPEP § 1204.01 which allows an applicant to reinstate an appeal after prosecution is reopened.

INTRODUCTION

The present invention is directed towards devices for removing undesired material or objects and maintaining or restoring patency of blood vessels or other luminal spaces. The devices of the present invention include structure that is linked or embodies a monolithic framework of thin struts which are radially expandable.

The invention is intended to provide a structure that has the capacity to engage and retain naturally occurring or foreign bodies while having a minimal profile that can traverse easily and repeatably through a standard catheter across tortuous anatomy. The device embodies superior flexibility to be deployed and retrieved consistently across difficult anatomy while being able to retain captured material.

The devices include an elongate member (i.e. a wire) and a body attached to the elongate member. The structure of the body can be made in a number of different ways. The bodies, i.e. baskets or cages, expand from a collapsed position to an expanded position to allow the body to engage and retain naturally occurring or foreign bodies in a body vessel. In one aspect, the body includes a structure which absorbs or modifies forces applied to the device when the elongate member is being manipulated by an operator. A filtering membrane portion intended to facilitate the capture of debris created during the interventional procedure can be attached to the body.

In other aspects of the invention, the structure of the body is defined by specific numbers of ribs members which interconnect specific numbers of ring

members to create distinct baskets or cages. The present application, U.S. Serial No. 10/680,602, was filed on October 6, 2003 and is a divisional application of Serial No. 09/919,507 filed on July 31, 2001 which is now U.S. Patent No. 6,660,021, which is a continuation-in-part application of Serial No. 09/469,431 filed on December 23, 1999, which is now U.S. Patent No. 6,402,771.

I. REAL PARTY IN INTEREST

The real party in interest in this appeal is ABBOTT CARDIOVASCULAR SYSTEMS INC. (formerly Advanced Cardiovascular Systems, Inc., the assignee of record), 3200 Lakeside Drive, Santa Clara, CA 95054, which is a division of Abbott Laboratories, 100 Abbott Park Road, Abbott Park, Illinois 60664-3500. This application was originally assigned by the inventors, OLIN PALMER; CHRISTOPHER T. SHEN; ROBERT LADUCA; LARRY J. VOSS; SAYPIN PHONTHALASA; JOHN E. PAPP; STEPHEN A. MORALES; COETA K. PELOQUIN; CHARLES R. PETERSON and ANUJA H. PATEL to ADVANCED CARDIOVASCULAR SYSTEMS, INC., by Assignment executed on September 4, 7, 10, 16, 20, 21, 25, 26, 2001 and January 4, 2002, which was recorded by the U.S. Patent Office on January 31, 2002 beginning at Reel 012542, Frame 0705.

II. RELATED APPEALS AND INTERFERENCES

With respect to other appeals or interferences that will directly effect, or be directly effected by, or have a bearing on the Board's decision on this appeal, it is to be noted that is believed there are no such appeals or interferences known to the Appellant.

III. STATUS OF CLAIMS

The status of the claims in this application is:

A. Total Number of Claims in the Application

The claims in the application are: Claims 1, 6 and 13-28. Claims 10 and 11 have been withdrawn in view of a restriction requirement. Original claims 2-5, 7-9 and 12 have been canceled without prejudice.

B. Status of All Claims on Appeal

Claims 1, 6 and 13-28 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,013,093 to Nott et al. (the "Nott patent").

Claim 1 was rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,347,846 to Dormia (the "Dormia patent").

C. Claims on Appeals

The claims on appeal are each of pending claims 1, 6 and 13-28. A copy of the claims being appealed is appended as Exhibit 1.

IV. STATUS OF AMENDMENTS

On February 20, 2009, the Examiner issued a final Office Action maintaining the §102 rejections of the pending claims. The finally rejected claims attached to this brief are the subject of this appeal.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The rejected claims are all directed to a device include an elongate member (i.e. a wire) and a body attached to the elongate member. The structure of the body can be made in a number of different ways. The bodies, i.e. baskets or cages, expand from a collapsed position to an expanded position to allow the body to engage and retain naturally occurring or foreign bodies in a body vessel. The body

includes a structure which absorbs or modifies forces applied to the device when the elongate member is being manipulated by an operator.

Independent Claim 1

Independent claim 1 is supported in the drawings and specification as follows:

1. An intravascular device for use in a body lumen, comprising:

an elongate member (page 34, lines 10-13) having a first end portion and a second end portion, the first end portion configured to extend exterior of the body lumen; and

a body (page 33, lines 6-10; FIG. 31; # 800) attached to the second end portion of the elongate member, the body being configured for deployment within the body lumen and including a substructure (page 33, lines 18-27; FIG. 31; # 804) that absorbs forces applied to the body of the elongate member, wherein the body has a proximal portion (page 33, lines 7-10; FIG. 31; # 802), a midsection (FIG. 31; between #802 and #812) and a distal portion (page 33, lines 11-13; FIG. 31; # 812), the proximal portion being attached to the elongate member.

Independent Claim 13

Independent claim 13 is supported by the drawings and specification as follows:

13. An embolic protection device for use in a body lumen, comprising:

an elongate member (page 34, lines 10-13) having a first end portion and a second end portion, the first end portion configured to extend exterior of the body lumen; and

a body portion (page 402, lines 1-5; FIG. 24; # 402), the body portion defined by a pair of rib members (page 30, lines 1-5; FIG. 24; # 414, 416) extending distally from the elongate member, each rib member branching into a pair of proximal ring members (page 30, lines 1-5; FIG. 24; # 420), each proximal ring member branching into pairs of distal ring members (page 30, lines 6-9; FIG. 24; # 430) to thereby define pairs of adjacent distal ring members converging into a plurality of single members (page 30, lines 9-12; FIG. 24; # 440) which converge to define a distal end of the body.

Independent Claim 19

Independent claim 19 is supported by the drawings and specification as follows:

19. An embolic protection device for use in vasculature, comprising:

an elongate member (page 34, lines 10-13) having a first end portion and a second end portion, the first end portion configured to extend exterior of vasculature; and

a body (page 30, lines 1-5; FIG. 24; # 402) having a proximal end portion (page 30, lines 1-5; FIG. 24; # 404) connected to the elongate member and which is defined by two pairs of rib members (page 30, lines 1-5; FIG. 24; # 414, 416), each rib member branching into pairs of proximal ring members (page 30, lines 1-5; FIG. 24; # 420) defining a first ring (page 30, lines 1-5; FIG. 24; # 422) which is connected by a plurality of links (page 30, lines 6-9; FIG. 24; #423) to a second ring (page 30, lines 6-9; FIG. 24; # 430) defined by distal ring members (page 30, lines 6-9; FIG. 24; # 430) to thereby define a midsection (page 30, lines 14-16; FIG. 24; between 404 and 436), extending distally from the midsection are a plurality of longitudinally extending members (page 30, lines 9-12; FIG. 24; # 440)

which converge to define a distal end portion (page 30, lines 9-12; FIG. 24; # 442) of the body.

Independent Claim 24

Independent claim 24 is supported by the drawings and specification as follows:

24. An embolic protection device for use in vasculature, comprising:

an elongate member (page 34, lines 10-13) having a first end portion and a second end portion, the first end portion configured to extend exterior of vasculature; and

a body (page 30, lines 1-5; FIG. 24; # 402) including four ribs (page 30, lines 1-5; FIG. 24; # 404) diverging from the elongate member, each rib branching into a pair of ring members (page 30, lines 1-5; FIG. 24; # 420) to thereby define pairs of adjacent ring members, each pair of adjacent ring members converging to define a link (page 30, lines 6-9; FIG. 24; # 423), extending distally from each link are a pair of second ring members (page 30, lines 6-9; FIG. 24; # 430) each of which converge into one of a plurality of terminal members (page 30, lines 9-12; FIG. 24; # 440) which are joined to define a distal end portion of the body.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Pursuant to the Final Office Action dated February 20, 2009, the claims were rejected as follows:

GROUND I

Independent claims 1, 13, 19 and 24, along with their dependent claims, were rejected under 35 U.S.C. § 102(b) as being anticipated by the Nott patent (Exhibit 2).

GROUND II

Independent claim 1 was rejected under 35 U.S.C. § 102(b) as being unpatentable over the Dormia patent (Exhibit 3).

VII. ARGUMENT

GROUND I

Appellant respectfully submits that the Examiner has misinterpreted the disclosure of the Nott patent. Claim 1 is directed to an intravascular device for use in a body lumen comprising an elongate member having a first end portion and a second end portion, the first end portion configured to extend exterior of the body lumen; and a body attached to the second end portion of the elongate member, the body being configured for deployment within the body lumen and including a substructure that absorbs forces applied to the body of the elongate member. Appellant notes that the Nott patent does not disclose a body (filter 10) **attached to** or **connected to** an elongate member as recited in claims 1, 6, 10, 11 and 19-23. The structure identified by the Examiner as the elongate member in the Nott patent is merely a pusher 134 which is not attached to the filter 10 (body), but rather, remains in an **abutting relationship** with the filter 10. The Examiner relies on the embodiment of Figures 5 and 5A for rejecting these claims. Appellant reproduces Figures 5 and 5A below for the convenience of the reader.

As can be seen in these drawings, the filter 10 is not attached to the pusher 134 since the filter 10 itself must remain implanted within the patient's vasculature (see Figure 5A). This pusher is not intended to remain attached to or connected to the filter 10 in any manner again since the filter 10 alone remains implanted in the vasculature.

FIG. 5

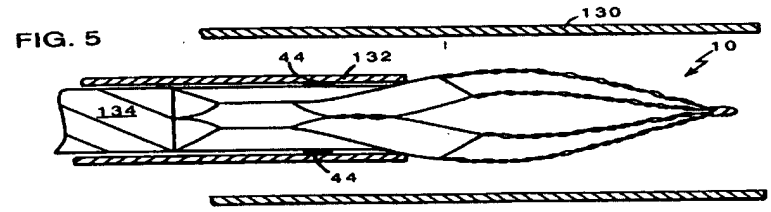
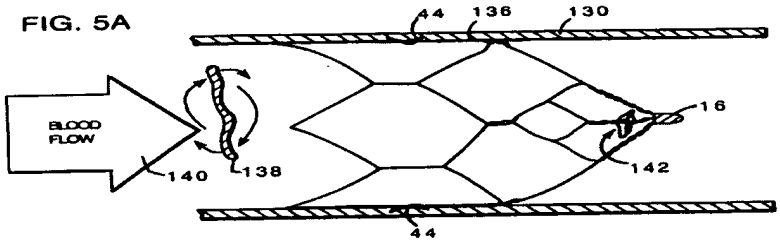


FIG. 5A



The Examiner takes the position that the Nott device, when given its broadest reasonable interpretation, shows that the body 10 is attached to the elongated member 134. However, Appellant believes that the Examiner's interpretation of the word "attached"' is not reasonable and goes well beyond this word's normal meaning. In the Nott patent, this pusher 134 is used to advance the filter 10 through a sheath 132 to the desired target location in the body vessel. Then, the filter 10 is released within the vessel as is shown in FIG. 5A. The sheath and pusher can then be withdrawn from the patient (see Col. 7, line 54 to Col. 8, line 2 of the Nott patent). This abutting arrangement of pusher 134 with the filter 10 does not constitute an "attached" or "connected" arraignment as the words "attached" and "connected" are normally construed. Moreover, Appellant's specification discloses an arrangement of an elongate member (guide wire) and body which are fixed to each other to allow **both** the body and the guide wire to remain in the patient's vasculature. Certainly, no one would dispute that the elongate member 134 disclosed in the Nott patent is not attached to the filter 10 once the filter 10 is deployed in the vessel as is clearly shown in Figure 5A. Accordingly, the Examiner's position that the pusher 134 of the Nott device is

somehow "attached" or "connected" to the filter 10 is incorrect and is based on an unreasonable interpretation of these words.

In the final Office Action dated September 11, 2008, the Examiner merely rejected the claims based on his position that the word "attached" was broad enough to cover elements which simply contact each other. In the final Office Action dated February 20, 2009, the Examiner includes a dictionary definition of the word "attached." The Examiner provides the following "dictionary" definition of the word "attached":

> at·tach
> [?]
> **–verb (used with object)**
> 1. to fasten or affix; **join; connect**: *to attach a photograph to an application with a staple.*
> 2. to join in action or function; make part of: *to attach oneself to a group.*
> 3. *Military.* to place on temporary duty with or in assistance to a military unit.
> 4. to include as a quality or condition of something: *One proviso is attached to this legacy.*
> 5. to assign or attribute: *to attach significance to a gesture.*
> 6. to bind by ties of affection or regard: *You always attach yourself to people who end up hurting you.*
> 7. *Law.* to take (persons or property) by legal authority.
> 8. *Obsolete.* **to lay hold of**; seize.
> **attach**
>
> *verb*
> 1. cause to be attached [ant: detach]
> 2. be attached; **be in contact with**

The Examiner's "dictionary definition" was apparently taken from web site http://dictionary.reference.com/browse/attach. Appellant has obtained the full dictionary definition of the word "attached" from this website. A copy of the various dictionary definitions generated by this site is attached as Exhibit 4. Appellant notes that the second listed verb definition provided by the Examiner above, namely,

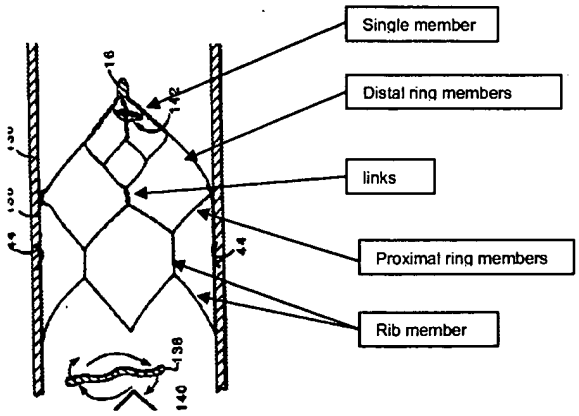
> *verb*
> 1. cause to be attached [ant: detach]
> 2. be attached; **be in contact with**

does not appear in any of the definitions provided in Exhibit 4. Most notably, this definition describes the word "attached" with the word itself, namely to "be

attached." Normally, a reputable dictionary source does not use the same term in defining that term, as the Examiner's verb definition does. Accordingly, Appellant refutes the validity of the Examiner's definition for the second listed verb definition for the word "attached" raised in the final Office Action. One skilled in the art would not consider the word "attached" to include simple contact between two components which are required to be separate from each other. Accordingly, one skilled in the art would not view the pusher 134 of the Nott patent as being attached to the filter 10.

Accordingly, the filter 10 of the Nott patent cannot possibly be attached to, or diverge from, or extend distally from, the elongate member, as recited in the claims, since the pusher 134 **must remain unconnected** from the filter 10 in order to implant the filter 10 as shown in FIG. 5A. The Examiner takes the position that the pusher 134 is at least temporarily attached to the filter when the pushed is delivering the filter in the lumen of the vessel. However, irregardless of the Examiner's "dictionary definition" for this term, mere contact between these two abutting component does not constitute an attachment or connection. For at least this reason alone, the Nott patent fails to disclose the basic structure recited in the pending claims.

Independent claims 13, 19 and 24 also require specific structural elements to be combined to create the body of the device. Claim 13 requires the body portion to be defined by a pair of rib members extending distally from the elongate member. Each rib member branches into a pair of distal ring members. Claim 13 requires the pair of ribs to extend distally from the elongate member. The Examiner has identified the various components making up the filter in the final Office Action. Appellant reproduces that drawing below for the convenience of the reader.



However, even assuming *arguendo* that the filter 10 extends distally from the elongate member, which Appellant strongly refutes above, the proximal end of the filter 10 identified appears to be made from a continuous ring member, not a pair of ribs as required in claim 13. Claim 13 requires the body portion to be defined by a pair of rib members extending distally from the elongate member. Figure 5A relied upon by the Examiner does not show this structure. Claim 13 further requires for each rib member to branch into a **pair** of proximal ring members. The structure identified by the Examiner as rib members do not branch into a pair of proximal rings. Although the Examiner identifies the Nott structure as having proximal ring members, only a single proximal ring is shown. Claim 13 further requires each proximal ring member to branch into pairs of distal ring members to thereby define pairs of adjacent distal ring members. Although the Examiner attempts to identify these distal ring members, the drawing of Figure 5A clearly shows the absence on any structure distal to the identified "links" which form anything which could conceivably form a ring. Accordingly, the Nott patent fails to disclose the particular structure recited in claim 13 for at least these reasons.

Claims 19 and 24 further require particular structure which cooperates to create the body of the embolic protection device. For example, claim 19 requires two pairs of rib members, each rib member defining a first ring which is connected by a plurality of links to a second ring defined by distal ring members. Again, Appellant submits that there is a complete lack of any structure distal to the identified "links" which even arguably form a distal ring. Additionally, claim 24 requires four ribs diverging from the elongate member, each rib branching into a pair of ring members. Again, a pair of proximal rings is simply not disclosed. Each pair of ring members in turn converges to define a link, which has been properly identified by the Examiner, and a **pair of second ring members extends distally from each link**. Again, this structure is lacking in the embodiment shown in Figure 5A above. Appellant submits that the Examiner has simply failed to present a prima facia showing of anticipation of the Nott patent with respect to all of the rejected claims.

Appellant notes that other elements recited in the claims are lacking in the Nott patent. For example, as noted above with respect the claim 1, the Examiner has notably **failed to identify any structure** in the Nott device that constitutes the "**substructure that absorbs forces applied to the body**" which are additionally recited in claims 18, 23 and 28. The Nott patent also fails to disclose the use of a **filter membrane** as recited in claims 14, 20 and 25. For at least these additional reasons, the Nott patent fails to anticipate the pending claims.

GROUND II

Claim 1 was rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,347,846 to Dormia (the "Dormia patent"). The Examiner states the following regarding the Dormia patent at page 4, paragraph 3 of the Office Action dated February 20, 2009:

> Dormia discloses substantially as claimed in figures 103, an elongated member (2, 3) having a first end portion configured to extend exterior of the body lumen; a body (8) attached to the second end portion of the elongate member (2, 3) and wherein the body (8) includes proximal and distal portion and midsection.

This is a verbatim rejection taken from the final Office Action dated September 11, 2007, which Appellant initially appealed. Appellant notes that while the Examiner later states in the Response to Arguments section of the Office Action that the Dormia patent includes a "substructure that absorbs forces applied to the body" as recited in claim 1, the Examiner has failed to identify any structure in the Dormia patent that constitutes this element. Appellant submits that the filter device disclosed in the Dormia patent lacks such a structure and that the Examiner has failed to provide a prima facia rejection of claim 1 based on the Dormia patent.

VIII. CLAIM APPENDIX

See Exhibit 1.

IX. EVIDENCE APPENDIX

See Exhibit 4.

X. RELATED PROCEEDINGS APPENDIX

NONE

XI. CONCLUSION

In summation, the Nott patent fails to disclose the basic elements recited in the pending claims and does not anticipate claims 1, 6 and 13-28. The Dormia patent also fails to disclose a basic element recited in claim 1. Accordingly, all of the pending claims have been incorrectly rejected by the Examiner.

The Commissioner is hereby authorized, however, to charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 06-2425.

Respectfully submitted,

FULWIDER PATTON LLP

/Thomas H. Majcher/
Thomas H. Majcher, Reg. No. 31,119

EXHIBIT 1

1. (Previously Presented) An intravascular device for use in a body lumen, comprising:

an elongate member having a first end portion and a second end portion, the first end portion configured to extend exterior of the body lumen; and

a body attached to the second end portion of the elongate member, the body being configured for deployment within the body lumen and including a substructure that absorbs forces applied to the body of the elongate member, wherein the body has a proximal portion, a midsection and a distal portion, the proximal portion being attached to the elongate member.

2-5. (Canceled)

6. (Previously Presented) The device of claim 1, the substructure being positioned at the midsection of the body.

7-9. (Canceled)

10. (Previously Presented) The device of claim 1, wherein the distal end portion of the body includes a distal tapered section, the distal tapered section including a coil having a tapered profile, the coil having a proximal end with tightly arranged coil sections and a distal end with relatively larger spaced coil sections.

11. (Previously Presented) The device of claim 1, wherein the distal end portion of the body includes a distal tapered section, the distal tapered section including ribs extending generally perpendicular to a longitudinal axis of the distal tapered section.

12. (Canceled)

13. (Original) An embolic protection device for use in a body lumen, comprising:

an elongate member having a first end portion and a second end portion, the first end portion configured to extend exterior of the body lumen; and

a body portion, the body portion defined by a pair of rib members extending distally from the elongate member, each rib member branching into a pair of proximal ring members, each proximal ring member branching into pairs of distal ring members to thereby define pairs of adjacent distal ring members converging into a plurality of single members which converge to define a distal end of the body.

14. (Original) The device of claim 13, further comprising a filter membrane attached to the body.

15. (Original) The device of claim 14, wherein the filter membrane defines a windsock configuration.

16. (Original) The device of claim 14, the filter membrane further comprising a plurality of pores.

17. (Original) The device of claim 14, further comprising a distal tapered section.

18. (Original) The device of claim 14, further comprising a substructure that absorbs forces applied to the body by the elongate member.

19. (Original) An embolic protection device for use in vasculature, comprising:

an elongate member having a first end portion and a second end portion, the first end portion configured to extend exterior of vasculature; and

a body having a proximal end portion connected to the elongate member and which is defined by two pairs of rib members, each rib member branching into pairs of proximal ring members defining a first ring which is connected by a plurality of links to a second ring defined by distal ring members to thereby define a midsection, extending distally from the midsection are a plurality of longitudinally extending members which converge to define a distal end portion of the body.

20. (Original) The device of claim 19, further comprising a filter membrane connected to the body.

21. (Original) The device of claim 20, wherein the filter membrane further comprising a plurality of pores.

22. (Original) The device of claim 20, further comprising a distal tapered section.

23. (Original) The device of claim 20, further comprising a substructure that absorbs forces applied to the body by the elongate member.

24. (Original) An embolic protection device for use in vasculature, comprising:

an elongate member having a first end portion and a second end portion, the first end portion configured to extend exterior of vasculature; and

a body including four ribs diverging from the elongate member, each rib branching into a pair of ring members to thereby define pairs of adjacent ring members, each pair of adjacent ring members converging to define a link, extending distally from each link are a pair of second ring members each of which converge into one of a plurality of terminal members which are joined to define a distal end portion of the body.

25. (Original) The device of claim 24, further comprising a filter membrane connected to the body.

26. (Original) The device of claim 24, wherein the filter membrane further comprising a plurality of pores.

27. (Original) The device of claim 24, further comprising a distal tapered section.

28. (Original) The device of claim 24, further comprising a substructure that absorbs forces applied to the body by the elongate member.

EXHIBIT 2

US006013093A

United States Patent [19]

Nott et al.

[11] Patent Number: 6,013,093

[45] Date of Patent: Jan. 11, 2000

[54] BLOOD CLOT FILTERING

[75] Inventors: Sepideh H. Nott, Newton; Hannah S. Kim, Boxborough; Naroun Suon, Lynn; David L. Sandock, deceased, late of Littleton, all of Mass., by Edna Ruth Sandock, executrix

[73] Assignee: Boston Scientific Corporation, Natick, Mass.

[21] Appl. No.: 08/849,392

[22] PCT Filed: Nov. 28, 1995

[86] PCT No.: PCT/US95/15365

§ 371 Date: Nov. 10, 1997

§ 102(e) Date: Nov. 10, 1997

[87] PCT Pub. No.: WO96/17634

PCT Pub. Date: Jun. 13, 1996

[51] Int. Cl.[7] A61B 17/00

[52] U.S. Cl. 606/200

[58] Field of Search 606/200, 191–199; 604/104; 623/1, 11, 12, 13

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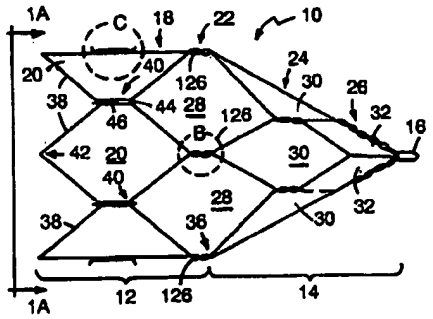
Primary Examiner—Michael Buiz
Assistant Examiner—Vikki Trinh
Attorney, Agent, or Firm—Hoffmann & Baron, LLP

[57] ABSTRACT

This invention is a blood clot filter having an anchoring portion (402) which includes a generally cylindrical self-expanding body. A generally conical filtering portion (400) is axially aligned with the cylindrical body (402), has an open proximal end (406) coupled to a distal end of the anchoring portion, and an apical distal end (404). In a preferred embodiment, the filter portion (400) is formed from strands (410) of resilient material that extend from the apical distal end (404) to the open proximal end (406). The strands (410) form twisted pairs (408) that converge at the apical distal end (404). The strands (410) diverge from the twisted pairs (408) in crossing paths to form a pattern of open filtering cells (A)(B)(C). The filter also has hooks (413) coupled to the anchoring portion (402) and formed from compliant material having an original shaped that bends under stress yet returns to its original shaped when unstressed.

45 Claims, 9 Drawing Sheets



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4,943,297	7/1990	Saveliev et al. .	
4,954,126	9/1990	Wallsten .	
4,957,501	9/1990	Lahille et al. .	
4,969,891	11/1990	Gewertz .	
4,990,156	2/1991	Lefebvre .	
5,059,205	10/1991	El-Nounou et al. .	
5,061,275	10/1991	Wallsten et al. .	
5,071,407	12/1991	Termin et al. .	
5,108,418	4/1992	Lefebvre .	
5,108,419	4/1992	Reger et al. .	
5,133,733	7/1992	Rasmussen et al. .	
5,135,516	8/1992	Sahatjian et al. .	
5,152,777	10/1992	Goldberg et al. .	
5,160,342	11/1992	Reger et al. .	
5,190,546	3/1993	Jervis .	
5,221,261	6/1993	Termin et al. .	
5,224,953	7/1993	Morgentaler .	
5,300,086	4/1994	Gory et al. .	
5,304,121	4/1994	Sahatjian .	
5,304,200	4/1994	Spaulding .	
5,324,304	6/1994	Rasmussen .	
5,329,942	7/1994	Gunther et al. .	
5,344,427	9/1994	Cottenceau et al. .	
5,370,657	12/1994	Irie .	
5,375,612	12/1994	Cottenceau et al. .	
5,382,261	1/1995	Palmaz .	
5,405,377	4/1995	Cragg	623/1
5,476,508	12/1995	Amstrup	623/1
5,522,822	6/1996	Phelps et al.	606/191 X
5,549,626	8/1996	Miller et al.	606/200
5,683,411	11/1997	Kavteladze et al.	606/200
5,709,704	1/1998	Nottt et al.	606/200

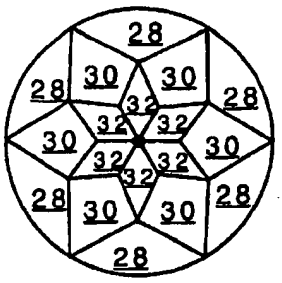

FIG. 1A

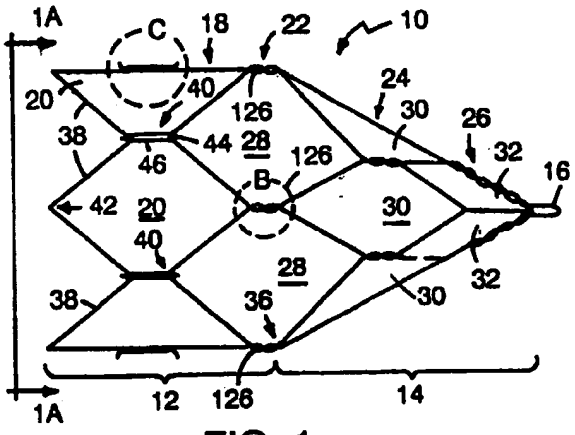

FIG. 1

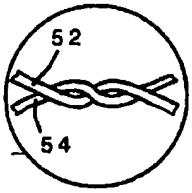

FIG. 1B

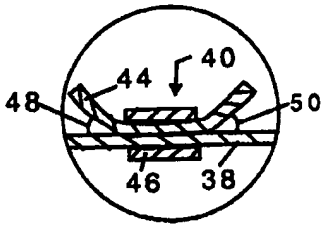

FIG. 1C

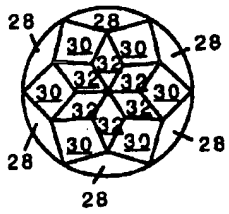

FIG. 2A

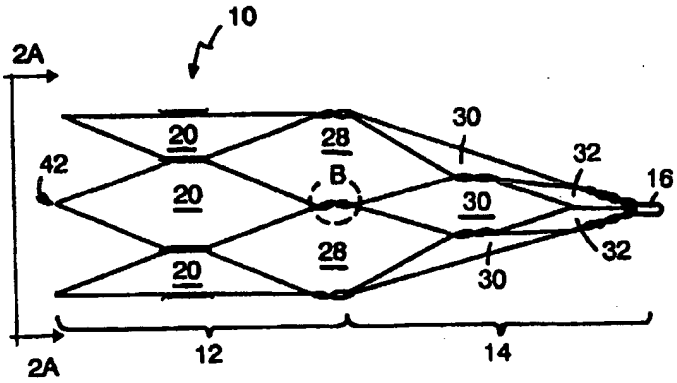

FIG. 2

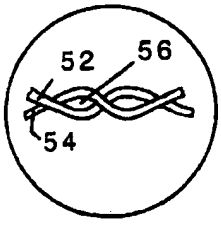

FIG. 2B

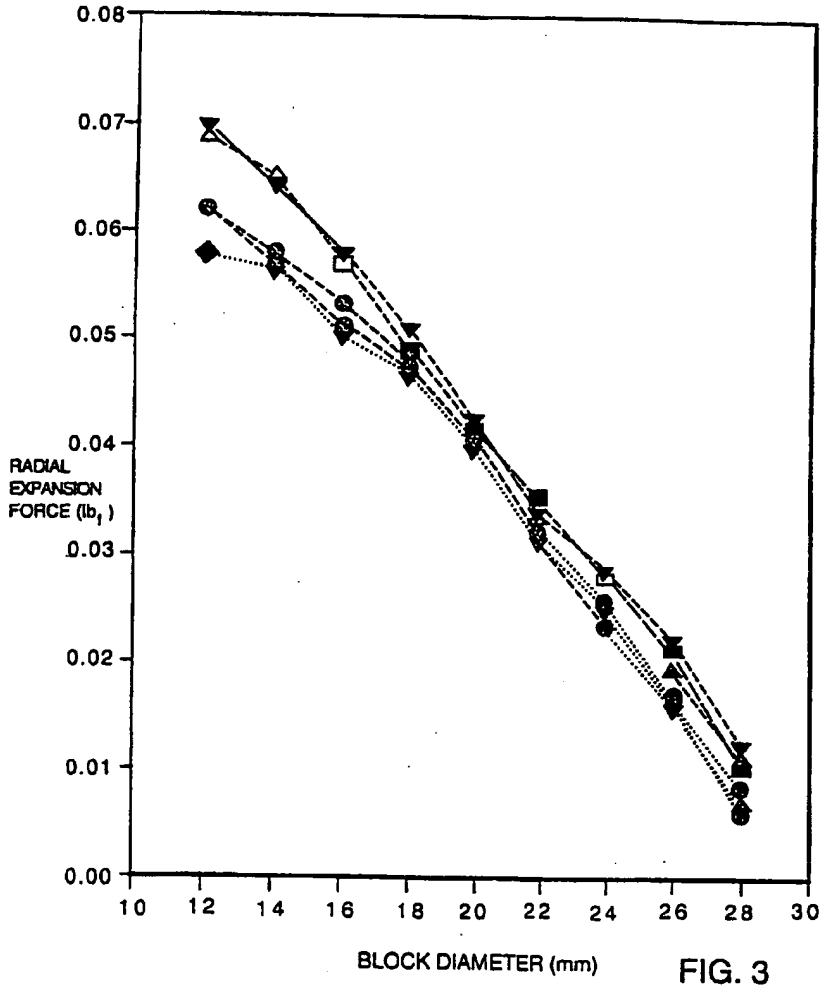
0.08
0.07
0.06
0.05
0.04
0.03
0.02
0.01
0.00
RADIAL EXPANSION FORCE (lb$_f$)
10 12 14 16 18 20 22 24 26 28 30
BLOCK DIAMETER (mm)

FIG. 3

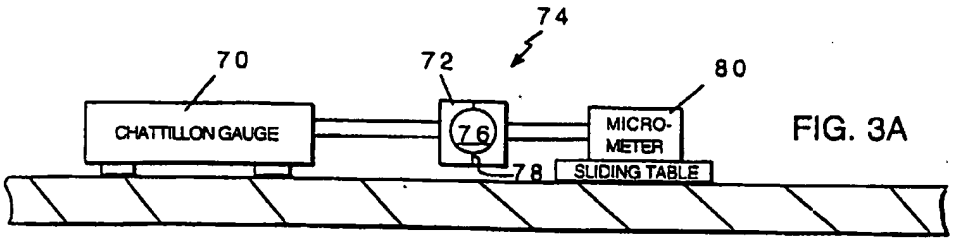
74
70
72
80
CHATTILLON GAUGE
76
MICRO-METER
78
SLIDING TABLE

FIG. 3A

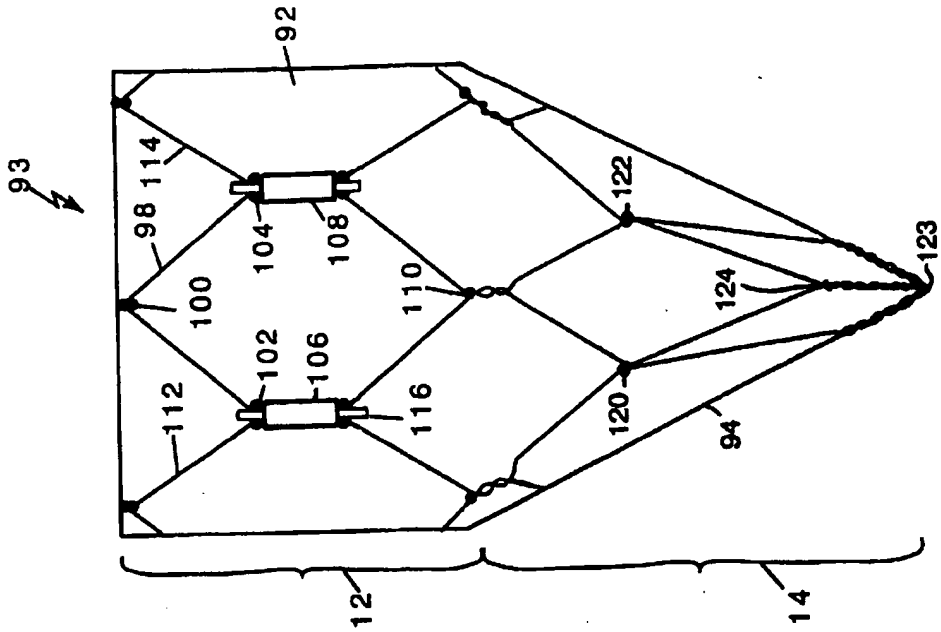
92
93
114
98
104
108
122
123
100
110
124
102
106
112
116
120
94
12
14

FIG. 4A

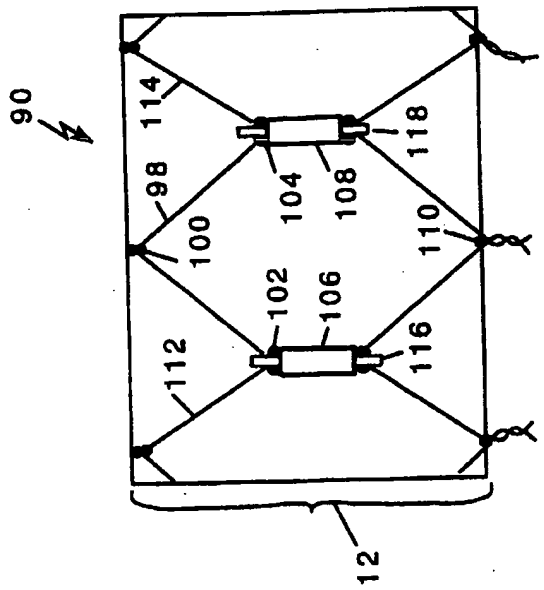
90
114
118
98
104
108
100
110
102
106
112
116
12

FIG. 4

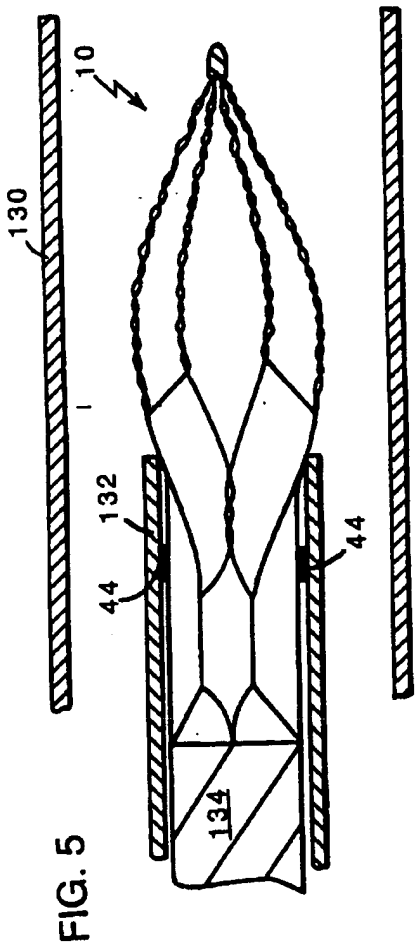

FIG. 5

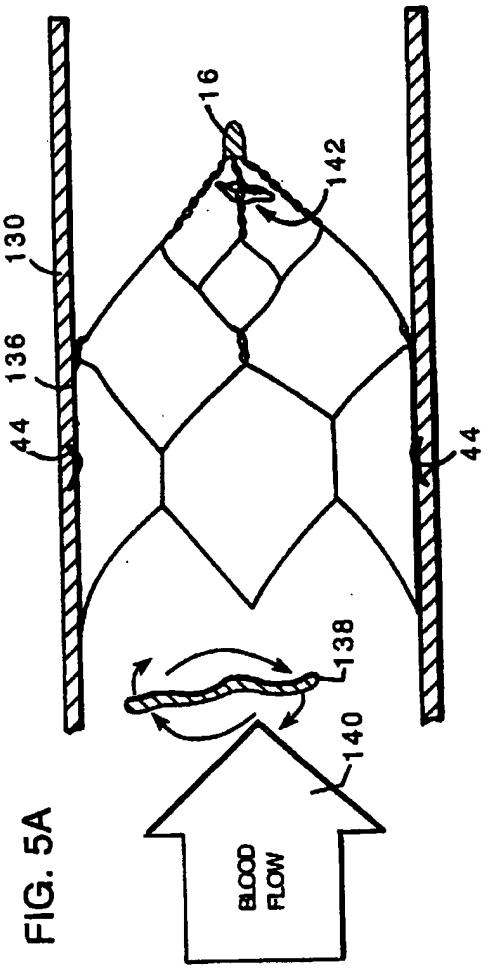

FIG. 5A

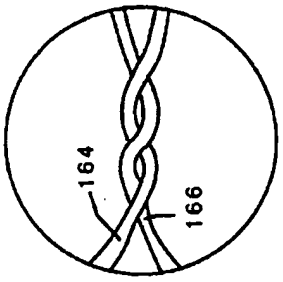

FIG. 6B

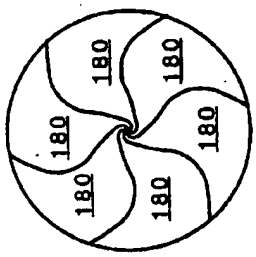

FIG. 7A

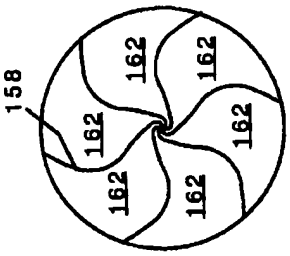

FIG. 6A

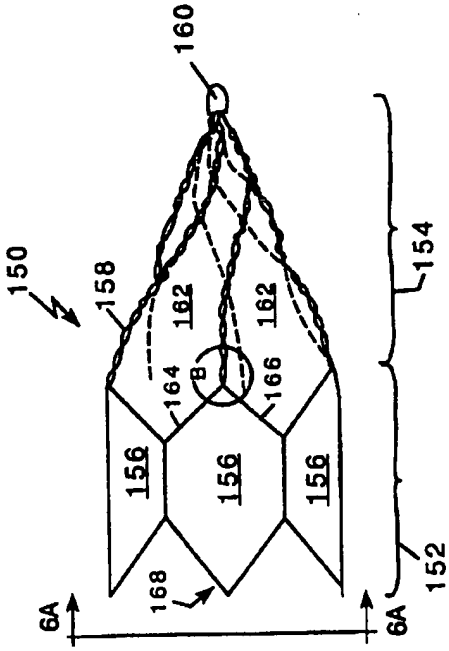

FIG. 6

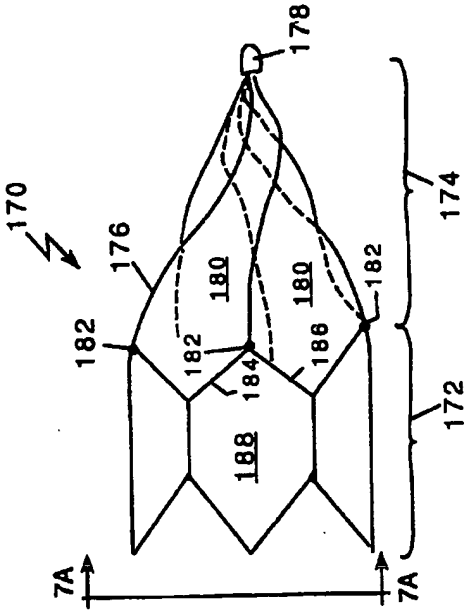

FIG. 7

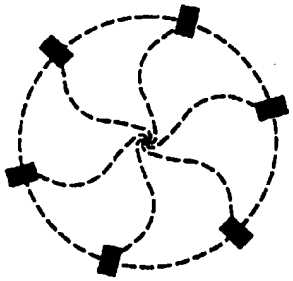

FIG. 8A

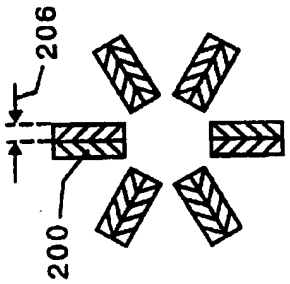

FIG. 8B

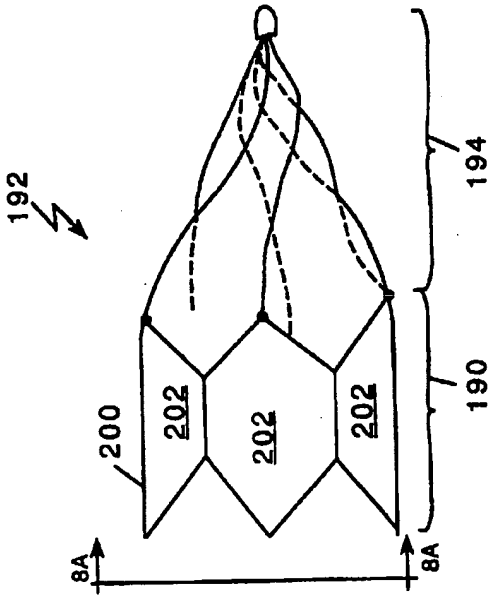

FIG. 8

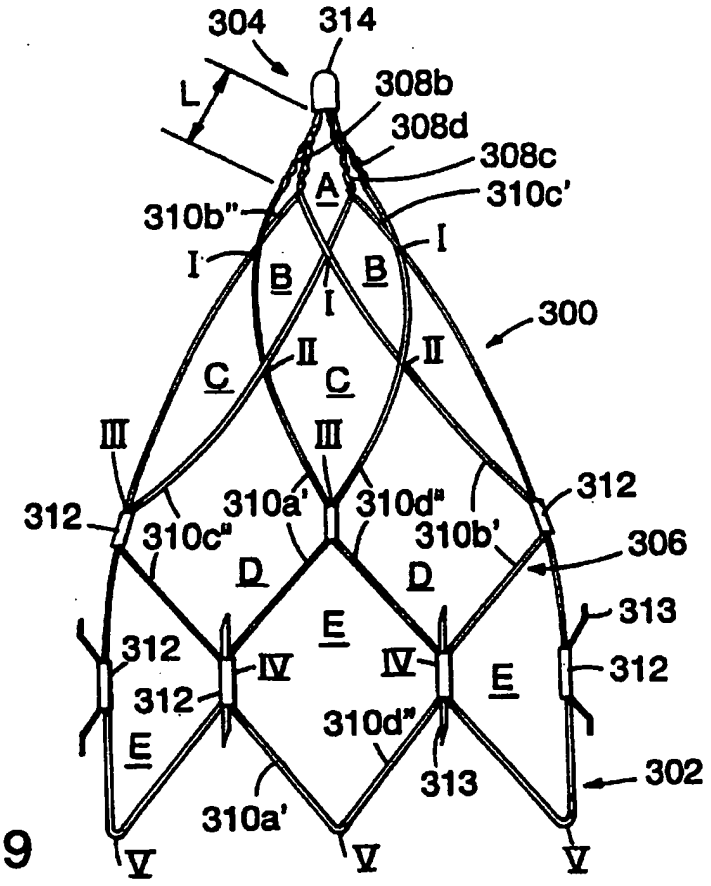
304
314
L
308b
308d
308c
310c'
310b"
A
I
B
300
C
II
III
312
310a'
310d"
310c"
310b'
306
D
E
313
IV
310d"
302
310a'
V

FIG. 9

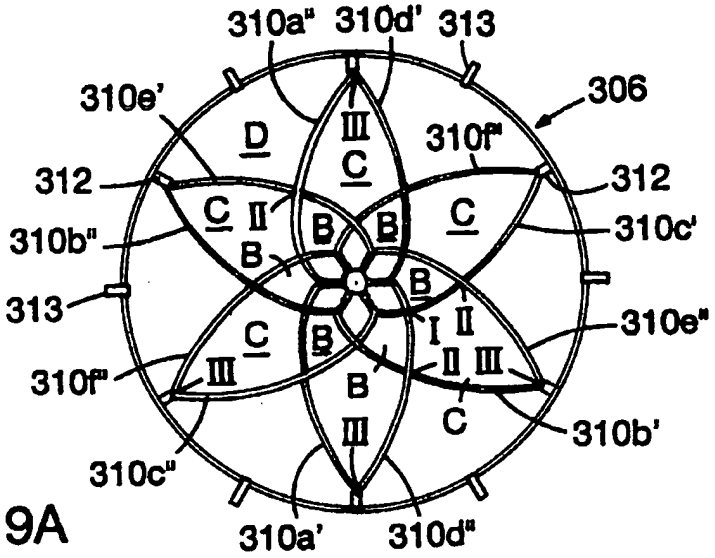
310a"
310d'
313
310e'
306
D
III
C
310f"
312
II
B
310b"
310c'
313
310e"
I
310f"
310b'
310c"
310a'
310d"

FIG. 9A

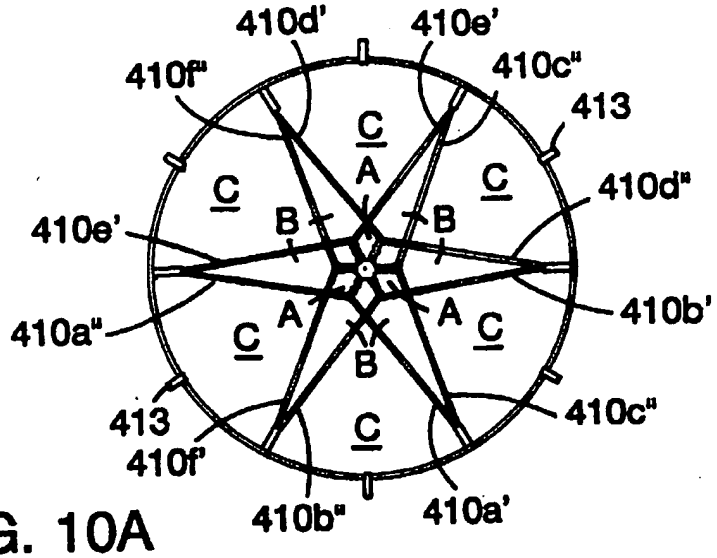

FIG. 10A

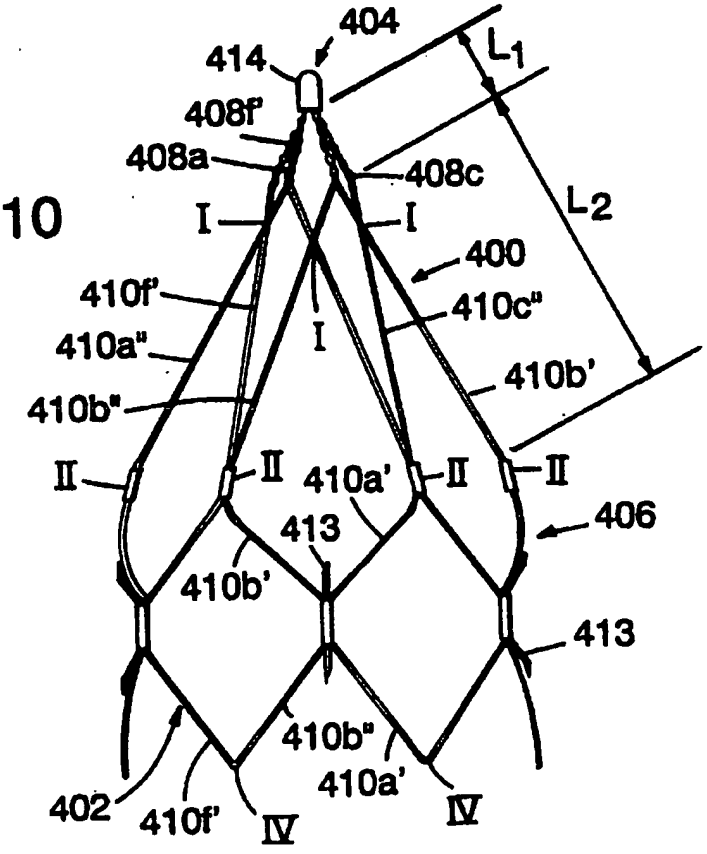

FIG. 10

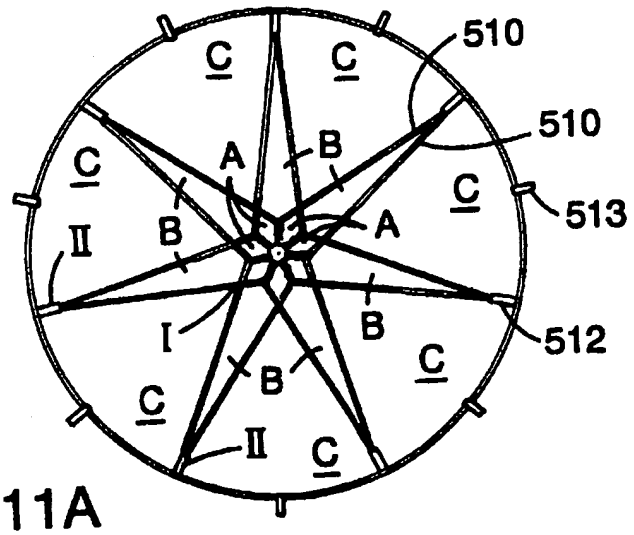

FIG. 11A

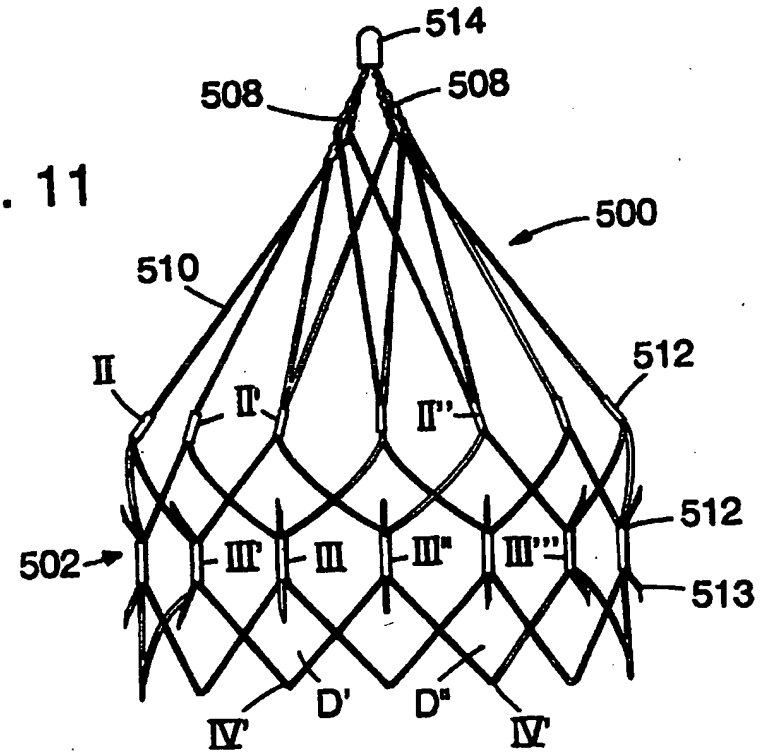

FIG. 11

BLOOD CLOT FILTERING

FIELD OF THE INVENTION

This invention relates to blood clot filtering.

BACKGROUND

Blood clots that form in the lower part of the body may migrate to the heart and may be subsequently pumped to the lungs. Small clots can be absorbed by the body without adverse effect. However, larger clots can interfere with the oxygenation of blood (e.g., on the order of 3 mm in diameter and 10–30 cm in length) and can possibly cause shock or sudden death.

Many transvenous filtering devices have been developed for installation in the vena cava to prevent especially large clots from reaching the lungs. These filters have fine wires positioned in the blood flow to catch and hold clots for effective lysing in the blood stream. Some of these devices are inserted into the vena cava by dissecting the internal jugular vein in the neck or the femoral vein in the groin, inserting a metallic capsule containing a filtering device to the proper position in the vena cava, and releasing the filtering device into the vena cava. More recently, filters have been designed for percutaneous introduction into the vasculature.

SUMMARY OF THE INVENTION

In one aspect, the invention features a filter sized and constructed to be compressed and passed through the vasculature of a patient to be anchored against an inner wall surface of a blood vessel for capturing blood clots in a blood stream passing therethrough. The filter comprises: an anchoring portion comprising a generally cylindrical self-expanding body formed from resilient material, the generally cylindrical body having proximal and distal ends and defining an axial direction and having a structure of variable size diameter expandable from a low-profile compressed condition to a larger profile expanded condition, wherein the resilient material urges the generally cylindrical body to radially expand and to thereby apply anchoring radial force against the inner wall surface of the blood vessel; and a generally conical filtering portion axially aligned with the generally cylindrical body having an open proximal end coupled to the distal end of the anchoring portion and having an apical distal end, the anchoring portion and the filtering portion being substantially non-overlapping to achieve a low profile compressed condition for delivery of the filter through the vasculature.

Embodiments of the invention may include one or more of the following features. The generally conical filtering portion is preferably formed from a plurality of elongated strands arranged to form a generally conical structure to guide blood clots in the blood stream flowing therepast to the apical distal end of the generally conical filtering portion for lysing. The elongated strands forming the generally conical filtering portion are constructed and arranged to maintain a generally conical shape whether the anchoring portion is in a compressed condition or an expanded condition. The anchoring portion and the filtering portion are preferably constructed and arranged so that the proximal end of the filtering portion conforms to the shape of the cylindrical body of the anchoring portion. The elongated strands are preferably fixedly attached to one another only at the apex of the generally conical filtering portion. The elongated strands may be formed from nitinol (nickel-titanium alloy), plastically deformable material, temperature-sensitive shape memory material with a transition temperature around body temperature, or elastic material having a core formed from radiopaque material. The filter may be coated with a drug for in vivo compatibility. The resilient elongated strands preferably extend from the proximal end of the anchoring portion to the distal apical end of the filtering portion.

The elongated strands of the filtering portion may define a plurality of neighboring filtering cells. According to one embodiment, the neighboring filtering cells are preferably loosely coupled together at the respective areas of contact between neighboring cells. The neighboring cells are preferably coupled together by helical twisting of portions of respective elongated strands of neighboring cells. The portion of the twisted-together elongated strands are preferably capable of slight mutual separation to accommodate changes in the shapes of the cells from the expanded to the compressed conditions.

According to another embodiment, the strands cross one another and are slidably movable relative to each other at their crossing regions.

The generally conical filtering portion preferably comprises at least two rings of cells, wherein the cells of each ring are of substantially equal size and are spaced substantially the same distance from the apical distal end of the filtering portion. The size of the cells in the rings is preferably smaller for cells closer to the apical distal end of the filtering portion than for cells located a greater distance from the apical distal end of the filtering portion.

The elongated strands may be twisted together in twisted groups of strands that converge at the apical distal end of the filter portion. The strands forming each twisted group may diverge from the twisted group and extend in paths therefrom to the open proximal end of the filter portion. Preferably, the twisted groups are twisted pairs of strands that diverge in either straight paths or spiralling paths that cross one another.

The elongated strands of the filtering portion may be spirally arranged with respect to one another from the proximal end of the filtering portion to the apical distal end of the filtering portion.

The elongated strands are preferably selected to have sufficient rigidity to maintain the generally conical shape of the filtering portion.

The self-expanding anchoring portion preferably comprises a ring of neighboring cells. The cells of the anchoring portion are preferably self-expanding. The cells of the anchoring portion preferably cooperate to urge the generally cylindrical body of the anchoring portion to radially expand from a compressed condition to an expanded condition. The neighboring cells of the anchoring portion are preferably fixedly coupled together at respective areas of contact. The cells of the anchoring portion are preferably formed from one or more resilient elongated strands. When the generally cylindrical body is in a compressed condition, the cells of the anchoring portion are preferably elongated in the axial direction.

In another general aspect, the invention features a blood clot filter comprising: an anchoring portion formed from resilient material having proximal and distal ends and having a generally circular transverse cross-section defining an axial direction, the anchoring portion further having a structure of variable size diameter expandable from a low-profile compressed condition to a larger profile expanded condition, wherein the resilient material urges the anchoring portion to radially expand and to thereby apply anchoring radial force

against the inner wall surface of the blood vessel; a filtering portion axially aligned with the generally cylindrical body having an open proximal end coupled to the distal end of the anchoring portion; and one or more hooks fixedly coupled to the anchoring portion formed from compliant material having an original shape that bends under stress yet returns to its original shape when unstressed, said one or more hooks respectively tending to project from the anchoring portion at an acute angle with respect to the axial direction for engagement with a vessel wall, the one or more hooks further being deflectable toward the anchoring portion for achieving a low-profile.

Embodiments of the invention may include one or more of the following features. The hooks are preferably formed from nitinol. The hooks preferably preferentially bend toward and away from the vessel wall engaging portion. The hooks are preferably formed from flat nitinol wire having a width dimension and having a thickness dimension substantially smaller than the width dimension for achieving preferential bending; the flat nitinol wire being oriented so that the thickness dimension of the flat nitinol wire coincides with a radial direction of the anchoring portion. The hooks preferably preferentially bend toward and away from the vessel wall engaging portion.

Among the advantages of the present invention are the following. Because the anchoring portion and the filtering portion have constructions that are optimally designed for their respective functions, the filter can have a low profile while providing a robust design that can readily accommodate different vessel sizes. Furthermore, the anchoring portion serves to center the filtering portion. The filtering portion of the filter should have a small enough capture cross-section to prevent large clots from passing therethrough. This requires a sufficient amount of filtering material (e.g., elongated strands) to reduce the capture cross-section. Since the conical filtering portion according to the present invention does not also have to support the filter in the vessel, smaller-sized elements can be used to form the filter to achieve a lower profile. The profile of the present invention can be made small, while providing substantially the same anchoring force and substantially the same filtering efficiency as, e.g., a GREENFIELD® 24 Fr stainless steel filter (available from Medi-Tech, Inc. of Watertown, Mass., U.S.A.). The filter designs minimally disturb blood flow, while achieving a desirable level of filtering efficiency. Since the sizes of the cells of the filtering portion decrease from the proximal end to the distal end, larger cells are positioned near the vessel walls where the flow velocity is relatively low and smaller cells are positioned in the central region of the vessel where the flow velocity is highest and where the most effective clot lysing occurs. Without being limited to a particular theory, it is believed that clots traveling with lower velocity do not pass through the larger size cells in the periphery of the conical filtering portion, but are instead guided to the apical distal end of the filtering portion. Clots traveling with higher velocities in the central region of the vessel, which may otherwise pass through the larger size peripheral cells, are caught in the smaller size cells located at the distal end of the filtering portion. Because the radial force against the vessel wall is distributed along a length of the vessel wall a filter according to the present invention offers higher resistance to migration as well as less trauma to the vessel wall.

Other features and advantages will become apparent from the following description and from the claims. For example, the invention features a process for making a blood clot filter and a method for treating a patient by implanting a blood clot filter into a blood vessel of the patient.

BRIEF DESCRIPTION OF THE DRAWING

FIGS. **1** and **1A** are diagrammatic side and end views of a filter in an expanded condition.

FIGS. **1B** and **1C** are enlarged views of respective portions of the filter shown in FIG. **1**.

FIGS. **2** and **2A** are diagrammatic side and end views of a filter in a compressed condition.

FIG. **2B** is an enlarged view of a portion of the filter of FIG. **2**.

FIG. **3** is a plot of radial expansion force provided by a filter as a function of the outer diameter of the filter.

FIG. **3A** is a diagrammatic side view of a system for measuring the radial force exerted by a filter as a function of the outer diameter of the filter.

FIGS. **4-4A** are diagrammatic side views of a filter and forming mandrels at different stages in a process for fabricating the filter shown in FIGS. **1–1***b* and **2–2B**.

FIG. **5** is a diagrammatic side view of a filter being delivered to a blood vessel.

FIG. **5A** is a diagrammatic side view of a filter anchored in a blood vessel.

FIGS. **6** and **6A** are diagrammatic side and end views of a filter.

FIG. **6B** is an enlarged view of a portion of the filter shown in FIG. **6**.

FIGS. **7** and **7A** are diagrammatic side and end views of a filter.

FIG. **8** is a diagrammatic side view of a filter.

FIGS. **8A** and **8B** are diagrammatic end views of the filter of FIG. **8** in an expanded condition and in a compressed condition, respectively.

FIGS. **9** and **9A** are diagrammatic side and end views of a filter in an expanded condition.

FIGS. **10** and **10A** are diagrammatic side and end views of a filter in an expanded condition.

FIGS. **11** and **11A** are diagrammatic side and end views of a filter in an expanded condition.

DETAILED DESCRIPTION OF THE INVENTION

Referring generally to FIGS. **1–1C** and **2–2B**, a blood clot filter **10** includes a generally cylindrical anchoring portion **12** and a generally conical filtering portion **14** terminating at a closed, distal apical end **16**. The cylindrical portion uniformly exerts an outward radial force to anchor the filter in a blood vessel (e.g., the vena cava) in which it is disposed; the exerted force being sufficient to prevent migration of the filter in the vessel. The generally cylindrical shape of the anchoring portion conforms to the inner wall surface of a blood vessel and properly centers the filtering portion within the vessel. The filtering portion provides a conical meshwork across the blood vessel to catch and retain clots in the blood stream.

Cylindrical portion **12** is formed by a ring **18** of circumferentially arranged cells **20**. Filtering portion **14** is formed by a series of three rings (**22, 24, 26**) of relatively loosely connected cells (**28, 30, 32**, respectively). The size of the cells forming the rings of the filtering portion increases from apical end **16** of the filtering portion to the proximal end **34** of the filtering portion, which is adjacent the distal end **36** of the anchoring portion.

Cells **20** of the cylindrical portion of the filter are defined by elongated strands **38** of resilient material (e.g., nitinol

wire). Neighboring cells are fixedly joined together at respective regions of contact **40**, e.g., by spot welding, as described in detail below. Fixed regions of contact **40** enable cells **20** in ring **18** to cooperate to urge the anchoring portion into an expanded condition (FIGS. 1–1B). The fixed regions of contact **40** also prevent the elongated strands forming cells **20** from rotating about each other, which might cause hinging and locking between the cells in a manner distorting the cylindrical shape of the anchoring portion. In a compressed condition (FIGS. 2–2B) the longitudinal length of cylindrical anchoring portion **12** increases.

Conical filtering portion **14** is constructed from a series of rings (**22, 24, 26**) of relatively loosely coupled cells in a manner preserving its generally conical shape, whether the filter is in a compressed condition or an expanded condition. The filtering portion does not need to provide anchoring radial force. However, the material substance forming the conical structure has sufficient structural integrity to prevent large clots in the blood flow from displacing the filtering structure. The size of the cells in the filtering portion are selected to minimally disturb the blood flow (which would otherwise encourage occlusion of the vessel), while still achieving a desired level of blood clot filtering.

In the embodiment shown in FIGS. 1–1C and 2–2B, the cells forming the filtering portion are coupled together by helically twisting together respective portions of the elongated strands defining neighboring cells. This coupling permits some rotation about the joints in a manner that preserves the generally conical shape of the filtering portion, whether the filter is in a compressed condition or an expanded condition.

Comparing FIGS. 1B and 2B, in the expanded condition (FIG. 1B), the twisted wire portions **52, 54**, coupling neighboring cells in the filtering portion of the filter, are tightly wrapped about each other. However, in a compressed condition (FIG. 2B), wire portions **52, 54** move away from (and rotate about) one another to form gaps **56**. This rotation or hinging prevents the build-up of internal forces within the filtering portion, which could cause the filtering portion to bow outward into a hemispherical shape, which would result in less effective blood clot filtering.

Referring back to FIG. **1C**, a hook **44** formed from a section of flat nitinol wire is disposed within a tube **46** (e.g., a hypotube) and mounted at regions of contact **40** between neighboring cells in ring **18**, which forms the cylindrical portion of the filter. A central region of hook **38** is mounted at regions of contact **40**. Hook **44** is bent at its proximal and distal ends to respectively form acute angles **48, 50** with respect to the longitudinal axis of the cylindrical portion. The bent ends of hook **44** are oriented in divergent direction to prevent migration of the filter in proximal and distal directions. The nitinol hooks easily bend to conform to the shape of the cylindrical surface of the anchoring portion to achieve a low profile for delivery of the filter. When the filter is released into a blood vessel, the hooks return to their bent shape for engaging an inner wall surface of the vessel. Fewer hooks may be used (e.g., three hooks symmetrically disposed about anchoring portion **12** may be used) to achieve a lower profile for delivery of the filter.

In a presently preferred embodiment designed for filtering blood clots in a vena cava of about 28 mm diameter, cylindrical portion **12** includes six cells formed from nitinol wire of 0.002–0.01 inch diameter, and preferably 0.008 inch diameter (e.g., nitinol with an A_f between −10° C. and +5° C. and constructed so that after drawing the wire has a tensile strength of about 250,000 psi to 300,000 psi, available from Shape Memory Applications of Sunnyvale, Calif., U.S.A.). Each cell in the anchoring portion has four side portions about 13 mm in length. Filter **10** is collapsible to a diameter of 0.08 inch (about 6 Fr). The anchoring portion has an expanded outer diameter of 30–31 mm.

The filtering portion includes three rings of cells of decreasing size from the proximal end **34** to the distal apical end **16**. Each of the proximalmost cells in the filtering portion has four side portions: two proximal side portions about 13 mm in length and two distal side portions about 15 mm in length. Each of the intermediate cells in the filtering portion has four side portions: two proximal side portions about 15 mm in length and two distal side portions about 11 mm in length. Each of the distalmost cells of the filtering portion has four sides portions: two proximal side portions about 11 mm in length and two distal side portions about 9 mm in length. The total length of the filter in the expanded condition is about 60 mm, with the filtering portion being about 32–34 mm in length and the anchoring portion being about 26–28 mm in length. Six hooks **44** are symmetrically disposed about the anchoring portion at each of the fixed regions of contact **40**. Hooks **44** are made from flat nitinol wire about 5 mm in length, about 0.5 mm in width and about 0.05–0.15 mm thick.

Referring to **FIG. 3**, the outward radial expansion forces respectively exerted by six different filters of the type shown in FIGS. 1–1C and 2–2B are plotted as a function of the outer diameter of cylindrical portion **12**. The measured filters were designed with the specifications recited above. The exerted force generally varies linearly with the diameter of the anchoring portion, with the highest forces being exerted when the filter is in the lower profile conditions (i.e., most compressed). Force levels of 0.01–0.07 pounds are generally acceptable for a typical vena cava of 12–28 mm diameter. Much higher force levels may cause the filter to undesirably distort the shape of the vena cava. Also, much lower force levels would not securely anchor the filter in the vena cava and the filter may be displaced.

The number of cells in the anchoring portion and in the filtering portion may be varied to achieve larger sizes or higher forces. For example, to accommodate a so-called "mega-cava" having a diameter of up to 40 mm, the expanded outer diameter of the filter should be selected to be about 42–44 mm and the number of cells in the anchoring portion should be appropriately increased (e.g., nine cells could be used) to achieve proper outward radial force exertion to anchor the filter in the vena cava without migrating or traumatizing the vessel. Instead of increasing the number of cells, the thickness of the wire used to form the cells could be suitably increased to provide the proper amount of anchoring force. Alternatively, the exerted radial force may be increased by providing additional welds at the distal end **36** (FIG. 1) of the anchoring portion at locations **126**. This increases the structural integrity of each cell **20**, providing higher spring force under compression. The exerted radial force may alternatively be increased by changing the wire alloy or the degree of cold work.

Referring to **FIG. 3A**, the outward radial force exerted by a filter was measured using a force gauge **70** (e.g., a Chattillon gauge) attached to one half **72** of a solid block **74** through which cylindrical hole **76** of a preselected diameter is disposed. Block **74** was cut in half through a plane containing the longitudinal axis of cylindrical hole **76**. A filter to be measured was placed in hole **76**. A micrometer **80** attached to the other half **82** of block **74** was used to close the gap between the two halves of block **74**. The force exerted by the filter was measured as a function of filter

diameter by performing the measurement with a series of blocks with different preselected diameters.

Referring to FIGS. **4** and **4A**, in a process for fabricating a filter **10**, a cylindrical thermally conductive mandrel **90** (e.g., formed from copper) is sized and constructed to conform to the desired filter size and shape. Mandrel **90** includes a plurality of anchoring pins protruding from its outer surface in a pattern corresponding to the desired cellular pattern for the filter.

As shown in FIG. **4**, the process for fabricating the anchoring portion of the filter includes the following steps. A wire strand **98** is bent around an anchoring pin **100** to form the proximal end of anchoring portion **12** of the filter. The two ends of wire strand **98** are pulled divergently downward to pins **102, 104** and through respective hypotubes **106** and **108**. The strands are bent convergently further downward to pin **110** (located about 23 mm distally from anchoring pin **100**), below which they are helically twisted about each other through two turns. The same steps are performed for neighboring strands **112** and **114**. Hooks **116, 118** are also passed through hypotubes **106, 108**. The respective hypotube assemblies are joined by resistance welding under an inert gas shield using about 70 ounces of force and about 10 Joules of heat.

As shown in FIGS. **4A**, the process for fabricating the filtering portion includes the following steps. The previously formed anchoring portion **12** of the filter is positioned about a cylindrical portion **92** of a mandrel **93** (e.g., formed from aluminum or stainless steel), which includes a conical portion **94**. The ends of strand **98** are pulled divergently downward to pins **120, 122** (located about 22 mm proximally from the distal end **123** of mandrel **91**), below which the strands are helically twisted through two turns with respective ends of neighboring strands **112, 114**. The ends of strand **98** are convergently pulled further downward to pin **124** (located about 8 mm proximally from the distal end **123** of mandrel **91**), below which the ends of strand **98** are helically twisted about each other through about 4–7 turns to the apical distal end of the filtering portion. The resulting six pairs of helically twisted strands are passed through a short hypotube (not shown), the top of which is TIG welded to securely fix all of the strands.

A metallic wire is wrapped about the filter/mandrel assembly to tightly secure the relative positions of the elongated wire strands defining the cells in the anchoring and filtering portions. The filter and the forming mandrel are then placed in an oven set to a temperature of about 450° C. for a period of 15 to 20 minutes. Prior to this heat treatment the nitinol wires are relatively malleable, but after heat treatment the nitinol wires strands preferentially maintain their shape. Once the mandrel has cooled the anchoring pins are removed and the filter is removed from the mandrel.

Referring to FIGS. **5** and **5A**, a blood clot filter **10** is delivered to a desired location within a vessel **130** (e.g., a vena cava having a diameter on the order of about 20 mm) through a previously inserted teflon sheath **132**. Sheath **132** having an outer diameter on the order of about 3 mm is inserted percutaneously, e.g., via a small opening (on the order of 9 Fr (about 0.117 inch)) in the groin and into the femoral vein of a patient. A pusher **134**, extending proximally to a location outside of the patient, is used to advance filter **10** through the sheath. Once the distal end of the sheath is properly positioned in vessel **130**, pusher **134** advances filter **10** to the distal end of the sheath and holds filter **10** in the desired position in the vessel. The sheath is then pulled back, releasing the filter within vessel **130**, as shown in FIG. **5A**. Once the filter is released, the sheath and the pusher can be withdrawn from the patient as a single unit.

Referring to FIG. **5A**, after the filter is released within vessel **130**, the self-expanding cells of the anchoring portion urge the anchoring portion to outwardly expand against an inner wall surface **136** of vessel **130** with sufficient force to prevent migration of the filter through the vessel. Within sheath **132** hooks **44** lie flat and conform to the shape of the cylindrical portion to allow the filter to slide through the sheath, but when the filter is released from the sheath the hooks spring outwardly from the anchoring portion of the filter for engagement with wall surface **136**. The expansion of the anchoring portion imbeds hooks **44** into the walls of the vessel to further secure the filter within the vessel.

We note that FIGS. **5** and **5A** are not drawn to scale, but instead are drawn diagrammatically for purposes of illustration.

In operation, the filter captures a blood clot **138** in blood flow **140** (e.g., on the order of 1 liter per minute) by guiding the clot to the apical distal end **16** of the filtering portion. Captured clots **142** are maintained in the central region of the blood flow where the velocity is highest to achieve the most effective lysing action.

As mentioned above, the sizes of the cells in the filtering portion are selected to be small enough to capture clots of a specified size with a desired level of efficiency (e.g., with clot capturing efficiency and patency comparable to a GREENFIELD® 24 Fr stainless steel filter, available from Medi-Tech, Inc. of Watertown, Mass., U.S.A.). Thus, it is desirable to reduce the size of the cells to increase the efficiency of clot capture. However, smaller cells create greater turbulence in the blood flow, encouraging clot formation on the filter that may result in the occlusion of a vessel. A filter according to the invention minimally disturbs blood flow, while achieving a desirable level of filtering efficiency. The sizes of the cells in the filtering portion decrease the closer they are to the apical distal end **16**. Thus, cell size in the filtering portion varies inversely with blood flow velocity: larger cells are positioned near the vessel walls where the flow velocity is relatively low and smaller cells are positioned in the central region of the vessel where the flow velocity is highest. Clots traveling with lower velocity do not pass through the larger size cells in the periphery of the conical filtering portion, but are instead guided to the apical distal end of the filtering portion. Clots traveling with higher velocities in the central region of the vessel, which may otherwise pass through the larger size peripheral cells, are caught in the smaller size cells located at the distal end of the filtering portion.

Other embodiments are also encompassed by the invention. Referring to FIGS. **6–6B**, a blood clot filter **150** includes a generally cylindrical anchoring portion **152** and a generally conical filtering portion **154**. Anchoring portion **152** includes a ring of cells **156** and is constructed in a similar manner as anchoring portion **12** of filter **10**, shown in FIGS. **1–1C** and **2–2B**. Filtering portion **154** is formed from six spirally arranged legs **158** terminating at an apical distal end **160**.

Legs **158** of the filtering portion of the filter are twisted through 90° over a length of about 32–34 mm. Twisting legs **158** creates a series of spirally arranged cells **162**. The projection of legs **158** in a plane transverse to the longitudinal axis of the anchoring portion reveals that the cells defined by legs **158** decrease in size from the peripheral edge of the filtering portion to the apical center; the amount of reduction being determined by the twist pitch (degrees of

rotation per unit length) and the number of legs **158** in the filtering portion. This reduction in cell size achieves an advantage similar to the advantage achieved by the reduction in cell size in the embodiment of FIGS. **1–1C** and **2–2B**, as described above.

As shown in FIG. **6B**, legs **158** are formed from pairs of elongated strands of resilient material (e.g., nitinol wire) **164, 166** helically twisted about each other. Strands **164, 166** correspond to the respective ends of strands **168** that are bent into a V-shape to form the proximal end of anchoring portion **152**. Twisting strands **164, 166** increases the rigidity of legs **158** for maintaining the structural integrity of the generally conical filtering portion. Increasing the rigidity of legs **158** also prevents clots from forcing their way past the filter by displacing the relative positions of the legs.

Referring to FIGS. **7-7A**, in another filter embodiment **170**, a generally cylindrical anchoring portion **172** is constructed in a similar manner as anchoring portion **12** of filter **10**, shown in FIGS. **1–1C** and **2–2B**. A generally conical filtering portion **174** is formed from six spirally arranged legs **176** terminating at an apical distal end **178**.

Legs **176** of filtering portion **174** are twisted through 90° over a length of about 32–34 mm, as in the filter embodiment shown in FIGS. **6–6B**, creating a ring of spirally arranged cells **180**. However, each leg **176** is formed from the continuation of a single elongated strand (formed from, e.g., nitinol wire) from the anchoring portion. To increase the structural integrity of the anchoring portion and the filtering portion, a series of spot welds **182** are provided at the distal end of the anchoring portion, joining strands **184, 186** that define cell **188**.

As shown in FIGS. **8–8B**, the anchoring portion **190** of a filter **192** may be formed from flat strands **200** (e.g., formed from superelastic material such as nitinol wire) having a rectangular cross-section. The anchoring portion of the filter is shown in an expanded condition in FIG. **8** and in a compressed condition in FIG. **8A**. The flat strands are arranged in the form of a ring of cells **202** (e.g., six cells), with the number and size of the cells being selected to provide a desired level of anchoring force. The width dimension **204** (on the order of 0.5–0.7 mm wide) of flat strands **200** is oriented radially and the thickness dimension **206** (on the order of 0.05–0.15 mm thick) is oriented circumferentially. This strand orientation provides a high radial force-to-compressed profile ratio. Also, use of flat strands facilitates manufacture of the filter because there is more strand material available for welding. A filtering portion **194** (e.g., a conical filtering portion) may be formed from spirally arranged wires as shown or may be formed from rings of cells, as in the filter of FIG. **1**. The filtering portion may be formed from the extension of flat strands **200**. Alternatively, a filtering portion may be formed from round wire that may be joined to the flat strand anchoring portion by welding with a hypotube arranged as a universal-type hinge, or by using an adhesive or sutures.

Referring now to FIGS. **9-9A**, another embodiment of a self-expanding filter, illustrated in an expanded condition, includes a substantially conical-shaped filter portion **300** that has a central apex **304** at one end and is joined at its other, open end **306** to an end of a cylindrical-shaped anchoring portion **302**. In the expanded condition, the open end of the filter portion is about 30–31 mm in diameter, and the filter portion has a mean length that is between about 30–40 mm.

Six pairs **308** of twisted strands **310** of resilient nitinol wire extend in a mutually twisted relationship from the apex **304** of the filter for a first distance L. Some of the strands **310** are hidden in the figures. The wire is preferably about 0.008 inches in diameter, and L can be between 0.2–0.5 inches and is preferably approximately 0.25 inches. The twisted pairs **308** diverge from each other as they spread from the center in paths substantially along the surface of an imaginary cone.

At the end of distance L, the strands **310** of each twisted pair **308** diverge from each other in opposite spirals. Strands **310**, spiralling in a first sense, are indicated in FIGS. **9** and **9*a*** by a single prime mark ', and strands spiralling in the opposite sense are indicated with a double prime mark ". The pairs of component strands **310** forming each of the twisted pairs **308** are distinguished by letters a–f.

The strands **310** continue along the surface of the imaginary cone, until adjacent strands cross each other at crossing regions, or nodes I. Each of a first ring of six open, generally diamond-shaped cells, A, is thereby defined. On two sides next to the center cells A are defined by adjacently located twisted pairs **308**, and on the two more distant sides by oppositely spiralling individual strands **310** that cross at nodes I. Each cell A shares a side formed from a twisted pair **308** with an adjacent cell A.

The strands **310** cross in an overall woven relationship at nodes I. Strand **310*a***' crosses over strand **310*b***", whereas at the next laterally adjacent node I, strand **310*b***' crosses over strand **310*c***", and so on, alternating about the central axis of the filter. The woven relationship establishes a slidable engagement of the crossing strands **310**, permitting the strands to slide relative each other at the nodes I during radial compression or expansion of the filter.

From nodes I the strands **310** continue in their generally spiralling relationship, progressing along the general surface of the imaginary cone. The strands **310** reach and cross further oppositely spiralling strand **310** at nodes II. The strands **310** again cross in a woven, slidable relationship such that each strand **310"** that passed under a strand **310'** at a node I now crosses over a different one of strands **310'** at a node II.

A second ring of six open, four-sided cells B that are each larger than cells A is thus defined adjacent cells A. Each cell B shares two short sides, located closest to the apical center **304**, with two adjacent cells A, and shares a node I with an adjacent cell B on each laterally spaced corner. The two short sides of each cell B are formed from strands **310** diverging from one of the twisted pairs **308**. For example, strands **310*a***' and **310*a***" form two sides of one of cells B, strands **310*b***' and **310*b***" form two sides of the next adjacent cell B, and so on. Two other, longer sides of each cell B are formed from oppositely spiralling strands diverging from the next adjacent twisted pairs **308**. For example, strands **310*b***" and **310*f*** form the long sides of one of cells B that has short sides formed from strands **310*a***' and **310*a***".

The strands **310** continue spiralling from nodes II until they reach joints at a third set of nodes III. A third ring of six open, four-sided cells C, each larger than cells B and A, is thus formed. A corner of each cell C closest the apical center of the filter portion is defined by one of nodes I. Two other corners farther from the apical center are formed from laterally adjacent nodes II. The fourth corner of each cell C is formed from one of nodes III. Two sides of each cell C closest to the apical center are formed by strands **310** that form adjacently located long sides of two adjacent cells B, for example strands **310*c***" and **310*b***'. Strands forming the two other long sides of the two adjacent cells B, in this instance strands **310*a***' and **310*d***", continue past nodes II to form two sides of that cell C farther from the apical center

304. While strands 310 joined at nodes III are not free to move relative to one another, strands 310 crossing at the other corners of cells C, at nodes I and II, are slidable relative to each other.

Strands 310 diverge from nodes III, although not in a spiralling fashion. For example, strands 310*a*' and 310*d*" diverge at node III and then join with strands 310*c*" and 310*b*', respectively, at nodes IV. A fourth ring of four-sided, open cells D is thereby formed, that are larger yet than cells A,B or C and lie close to parallel with the direction of flow Z. The strands forming each of cells D are fixed together where they cross at two nodes III and one node IV, but are slidable relative to each other at one node II.

The strands connecting between nodes III and IV define the open end 306 of the conical filter portion 300. These strands 310 also form a boundary for one end of the anchoring portion 302. The anchoring portion 302 is formed of a fifth ring of six diamond-shaped, open cells E, that lie along the inner wall of the blood vessel, parallel to the direction of blood flow. In the expanded configuration, the anchoring portion 302 is preferably approximately 25 mm long and approximately 30–31 mm in diameter.

Strands forming two sides of each cell D that are farthest from the apical center 304 also form sides of two adjacent cells E. The strands diverge at nodes IV and intersecting strands are joined again at nodes V. In the preferred embodiment shown in FIG. 9, for example, strands 310*a*' and 310*d*" diverge from node III, are joined to strands 310*c*" and 310*b*', respectively at adjacent nodes IV, and diverge from nodes IV and are joined again at node V, which, in this embodiment, is actually a bend in a single strand. In some applications, it may be desirable to form a longer anchoring portion by simply forming one or more additional rings of diamond-shaped, open cells that lie along the lumen wall.

Strands 310 are joined at nodes III and IV by positioning a small cylindrical sleeve 312 around a pair of strands and then by welding or crimping the sleeve 312 to the strands. The twisted pairs 308 are joined where they converge at the apex 404 by positioning a sleeve 314 over them and then welding or crimping the pairs 308 and the sleeve together.

Hooks 313 are coupled to the anchoring portion 302 at nodes IV for engaging the inner wall of a blood vessel such that the filter will not slip out of position once emplaced.

The structure of cells A, defined by the twisted pairs 308 in the region adjacent to the center 304 of the filter portion 300, achieves an open area that is relatively large in the central region of greatest blood flow rate in comparison to the case that would exist if the same number of strands 310 commenced their independent spiralling at the center of the filter unit 300. The relatively open geometry obtained by twisting the strands 310 into pairs 308 before joining them at the center 304 enhances blood flow and clot-lysing action and reduces any tendency for forming new clots on the filter.

The relatively large openings of cells A, and the progressively larger cells B, C and D, while providing a relatively low flow resistance, are small enough to capture clots effectively, given the respective aspect angles that they present to the flow.

Each filter cell A, B, C and D in this embodiment has at least one node formed by crossing strands that can slide relative to each other when the filter is radially or longitudinally deformed. Cells B and C intermediate the extremities of the conical structure have such slidable engagement at three nodes.

The strands 310 spiral in gently arcuate paths between the twisted pairs 308 and nodes III. There are no sharp bends in the strands where they cross at nodes I or II. This feature enhances the ability of the strands 310 to slide relative to each other at their crossing regions. The woven, crossing, and slidable relationship of the strands 310 at the nodes I and II in this embodiment produces a structural integrity sufficient to maintain the desired conical structure and filtering aspect, while having a degree of sliding self-adjustability when compressed or expanded that contributes to the filter's ability to conform to various size vessels.

Referring now to FIGS. 10 and 10A, another embodiment of a self-expanding filter, illustrated in an expanded condition, includes a substantially conical-shaped filter portion 400 that has a central apex 404 at one end and is joined at its other, open end 406 to an end of a cylindrical-shaped anchoring portion 402. Like the filter illustrated in FIGS. 9 and 9A, this filter is about 28–30 mm in diameter in the expanded condition and the filter portion is about 30–40 mm long.

Six twisted pairs 408*a–f* of elongated strands 410 of nitinol wire extend from the apex for a distance L_1 along the surface of an imaginary cone. The strands 410 forming each twisted pair 408 then diverge from each other at an angle and continue toward the open end 406 in approximately straight paths along the surface of the imaginary cone. Some of the strands 410 and twisted pairs 408 are hidden in the figures. The strands are referenced by letters *a–f* to indicate the twisted pairs from which they respectively originated. L_1 can range between about 0.2–0.5 inches, and is preferably about 0.25 inches.

A first group of the strands 410 that diverge from the twisted pairs 408 in one direction, indicated by a single prime ', each cross under a strand 410 from an adjacent twisted pair 408 that diverges in the other direction, the second group of strands being indicated by a double prime". For example, strand 410*a*' crosses over strand 410*b*", strand 410*b*' crosses under strand 410*c*", etc. The strands 410 are slidably movable relative to each other at the crossing regions, or nodes I, during expansion and compression of the filter.

A first ring of six diamond-shaped open cells A is formed by the twisted pairs 408 and the crossing strands 410. Each cell A has two sides near the apex 404 that are formed from adjacent twisted pairs 408, and two sides farther from the apex 404 that are formed from crossing strands 410 that diverge from those two twisted pairs. For example, one of cells A is formed from twisted pairs 408*a* and 408*b*, and strand 410*a*' that crosses under strand 410*b*".

The strands 410 continue in substantially straight paths from nodes I to the open end 404 where pairs of strands are coupled together at nodes II, thereby defining a second ring of six diamond-shaped, open cells B. The distance L_2 between the points of divergence of the strands 310 forming the twisted pairs 308 and the nodes II is preferably approximately 1.1 inch. Each of cells B is defined on two sides nearest the apex 404 by the two strands 410 that diverge from one of the twisted pairs 408 and the two strands from adjacent twisted pairs that cross the first two strands. For example, one of cells B is formed on two sides from strands 410*a*' and 410*a*" that diverge from twisted pair 408*a*, and on two other sides from strands 410*f*" and 410*b*' that cross strands 410*a*' and 410*a*" respectively.

The strands 410 diverge from nodes II and are each joined, at nodes III, with a strand diverging from an adjacent node II, thereby forming a third ring of cells C adjacent the open end 406 of the filter portion 400. For example, one of cells C is formed from strands 410*a*' and 410*b*" that cross at

a node I, are joined to strands 410c" and 410f' respectively at adjacent nodes II, and each diverge therefrom and are joined at a node III. Each of cells C includes only one crossing region, node I, at which the strands are slidably movable relative to each other.

The anchoring portion is formed from a fourth ring of six diamond-shaped cells D, each cell D sharing a side with each of two neighboring cells C. The same strands that diverge from a node II at one corner of each cell D again join at a node IV at an opposite corner of the cell. Adjacent nodes III form the other two corners of each cell D. For example, nodes II', III', IV' and III" form the corners of cell D', and nodes II", III", IV" and III"' form the corners of an adjacent cell D".

Filter portion **400** has one fewer ring of cells than filter **300**. Cells A and C are each formed from strands forming only one crossing region I where the strands are slidably movable relative to each other. The strands or twisted pairs forming each of cells A and C are joined together at their other corners. There is only one intermediate ring of cells B, and these cells each have only two nodes I where the strands are slidably movable relative to each other.

The strands **410** diverging from the twisted pairs **408** in filter **400**, like the strands **310** in filter **300**, do not exhibit any sharp bends that would interfere with their ability to slide relative to each other. This feature permits a smooth transition from the compressed state to the expanded condition.

Referring now to FIGS. **11** and **11A**, another embodiment of a filter intended for use in an especially large vena cava has an expanded diameter of about 40–43 mm. This embodiment is similar in most respects to the embodiment illustrated in FIGS. **10** and **10A**, however, it has an extra pair of strands **510**. Each coaxial ring of cells in the filter portion **500** has three coaxial rings of cells A, B, and C, and the anchor portion **502** has one ring D. Each ring includes seven cells instead of the six cells in each ring in the embodiment illustrated in FIGS. **10** and **10A**.

Cells A and C each include one crossing region I of strands that are slidably movable relative to each other, and cells B each include two such crossing regions I. The strands defining cells D of the anchor portion **502**, however, are joined together at their crossing regions. For example, nodes II', III', IV' and III" form the corners of cell D', and nodes II", III", IV" and III"' form the corners of an adjacent cell D".

In each of the embodiments illustrated in FIGS. **10** and **11**, the strands **410**, **510** are joined at nodes III and IV by positioning a small cylindrical sleeve **412**, **512** around a pair of strands and then by welding or crimping the sleeve **412**, **512** to the strands.

Hooks **413**, **513** are coupled to the anchoring portions **402**, **502** at nodes III for engaging the inner wall of a blood vessel such that the filter will not slip out of position once emplaced.

Although the invention has been described in connection with blood clot filtering in the vena cava, the present invention would also be useful for filtering clots in other areas of the vascular anatomy. For example, blood clot filtering may be useful in vessels leading to the brain. The filter used in such applications would be constructed of appropriate size and of appropriate material to provide proper anchoring force against an inner wall surface of the vessel in which the filter is disposed.

In further embodiments, the respective strands **38** and hooks **44** in regions of contact **40** (FIG. **1**) in the anchoring portion of the filter may be joined together using laser welding along a length of about, e.g., 2–3 mm, instead of using a hypotube and resistance welding.

In other embodiments, the filter may be of the non-self-expanding type, preferably delivered using a catheter having an expandable balloon. The cells can be made of plastically deformable material, which may be, for example, tantalum, titanium, or stainless steel.

In still other embodiments, the filter may be formed of a temperature-sensitive shape memory material with a transition temperature around body temperature. The filter may then be delivered in a compressed condition in one crystalline state and expanded by crystalline phase transformation when exposed to body temperature.

In other embodiments, at least a portion of the filter may be formed from nitinol wire having a core of tantalum wire or other radiopaque material, as described in U.S. Ser. No. 07/861,253, filed Mar. 31, 1992 and U.S. Ser. No. 07/910,631, filed Jul. 8, 1992, both of which are herein incorporated by reference. This enhances the radiopacity of the filter so that the filter may be viewed using X-ray fluoroscopy to monitor placement and operation of the filter.

In still other embodiments, the filter may be coated with a drug for in vivo compatibility prior to delivery into the body. For example, the filter may be coated with heparin, as described in U.S. Pat. Nos. 5,135,516 and 5,304,121, which are herein incorporated by reference.

Other embodiments are within the scope of the claims.

We claim:

1. A filter sized and constructed to be compressed and passed through the vasculature of a patient to be anchored against an inner wall surface of a blood vessel for capturing blood clots in a blood stream passing therethrough, said filter comprising:

an anchoring portion comprising a generally cylindrical self-expanding body formed from resilient material, said generally cylindrical body having proximal and distal ends and defining an axial direction and having a structure of variable diameter that is expandable from a low-profile compressed condition to a larger profile expanded condition, wherein said resilient material urges said generally cylindrical body to radially expand and to thereby apply anchoring radial force against the inner wall surface of the blood vessel; and

a filtering portion aligned with said generally cylindrical body, and having an open proximal end supported near the distal end of said anchoring portion, wherein the filtering portion includes elongated strands structured to provide a capture cross-section that prevents large clots from passing therethrouqh.

2. The filter of claim **1** wherein said anchoring portion and said filtering portion are substantially non-overlapping to achieve a low profile compressed condition for delivery of the filter through the vasculature.

3. The filter of claim **2**, wherein said filtering portion is formed from a plurality of the elongated strands arranged to form a generally conical structure to guide blood clots in the blood stream flowing therepast to an apical distal end of said generally conical filtering portion for lysing.

4. The filter of claim **3** wherein said elongated strands are fixedly attached to one another only at the apex of said generally conical filtering portion.

5. the filter of claim **3**, wherein said elongated strands define a plurality of neighboring filtering cells.

6. The filter of claim **5**, wherein the cells are arranged in a plurality of coaxial rings of neighboring cells, each ring being progressively more distant from the apical distal end and having cells that are larger than the cells of the ring next closest the apical distal end.

7. The filter of claim 6, wherein neighboring filtering cells are loosely coupled together at the respective areas of contact between neighboring cells.

8. The filter any of claim 5, wherein neighboring cells are coupled together by helical twisting of portions of respective elongated strands of neighboring cells.

9. The filter of claim 7 wherein the portion of the twisted together elongated strands are capable of slight mutual separation or rotation to accommodate changes in the shapes of said cells from the expanded to the compressed conditions.

10. The filter as in any one of claims 3–6, wherein said elongated strands are spirally arranged from the proximal end of said filtering portion to the apical distal end of said filtering portion.

11. The filter of claim 3, wherein said elongated strands are selected to have sufficient rigidity to maintain the generally conical shape of said filtering portion in a flowing blood stream.

12. A filter sized and constructed to be compressed and passed through the vasculature of a patient for anchoring against an inner wall surface of a blood vessel for capturing blood clots in a blood stream passing therethrough, said filter comprising:

a cylindrical anchoring portion having proximal and distal ends and defining an axial direction and having a structure of variable size diameter expandable from a low-profile compressed condition to a larger profile expanded condition; and

a filter axially aligned with said generally cylindrical body having an open proximal end supported from the distal end of said anchoring portion and having a distal end, said filter defined by elongated spiral strands,

wherein said cylindrical anchoring portion and said filter are substantially nonoverlapping to achieve a low profile compressed condition for delivery of the filter through the vasculature.

13. A filter having a longitudinal axis, sized and constructed to be compressed and passed through the vasculature of a patient and to be expanded and anchored against an inner wall surface of a blood vessel for capturing blood clots in a blood stream passing therethrough, said filter comprising a filter portion having a closed distal end and an open proximal end, the filter portion comprising two sets of strands formed of resilient material that spiral in opposite directions in a crossing pattern that defines a plurality of open cells, the strands being slidably movable relative to each other at regions where they cross.

14. The filter of claim 13, wherein the cells are arranged in a plurality of rings of neighboring cells, each ring being progressively more distant from the distal end and having cells that are larger than the cells of the ring next closest the distal end.

15. The filter of claim 14, wherein the cells of a first ring closest to the, distal end each comprise two sides closest to the distal end that are formed of twisted pairs of the strands, and wherein the strands of each twisted pair diverge from the twisted pair in the opposite spiral directions.

16. The filter of claim 15, wherein the twisted pairs converge at the distal end.

17. The filter of claim 14, wherein the plurality of rings comprises:

a ring nearest to the, distal end, comprised of cells each including only one of the crossing regions of relatively slidable strands;

a ring nearest the open end comprised of cells each including only one of the crossing regions of relatively slidable strands; and

at least one intermediate ring comprised of cells each including only three of the crossing regions of relatively slidable strands.

18. A filter sized and constructed to be passed through the vasculature of a patient in a compressed condition and to be anchored in an expanded condition against an inner wall surface of a blood vessel for capturing blood clots in a blood stream passing therethrough, said filter including a filter portion that is substantially conical-shaped in the expanded condition and having an apical distal end and an open proximal end, the filter portion comprising two sets of strands of spring material that spiral in opposite directions in a crossing pattern, the strands being relatively slidable at regions where they cross, in the expanded condition the crossing pattern defining a plurality of four-sided, open cells, the cells being arranged in rings having a common axis, the cells of each ring being progressively larger with distance from the apical center, a first ring nearest to the apical center comprised of cells each including only one of the crossing regions of relatively slidable strands, at least one intermediate ring comprised of cells each including at least two of the crossing regions of relatively slidable strands, and a third ring nearest the open end comprised of cells each including only one of the crossing regions of relatively slidable strands, wherein the cells of the first ring each comprise two sides closest to the apical center that are formed of twisted pairs of the strands, wherein the twisted pairs join at the apical center.

19. A filter having a longitudinal axis, said filter sized and constructed to be passed through the vasculature of a patient in a radially compressed condition and to be anchored against an inner wall surface of a blood vessel in a radially expanded condition for capturing blood clots in a blood stream passing therethrough, said filter comprising a filter portion that includes a distal end, an open proximal end of variable size diameter, and elongated strands extending from the distal end to the open proximal end, the strands being twisted together in twisted groups which converge at the distal end to define common borders of a plurality of open filtering cells.

20. The filter of claim 19, wherein the twisted groups of strands are twisted pairs of strands that converge at the distal end.

21. The filter of claim 19, wherein the strands forming each of the twisted groups diverge from each other at a location between the distal end and the open proximal end and extend in paths therefrom to the open proximal end, the strands diverging from the twisted groups and the twisted groups together defining the plurality of open cells.

22. The filter of claim 21, wherein the path of each strand diverging from the twisted groups crosses the path of at least one other strand diverging from the twisted groups.

23. The filter of claim 22, wherein the strands diverging from the twisted groups are slidably movable relative to each other at regions where they cross.

24. The filter of claim 21, wherein each strand is joined to another strand at the open proximal end.

25. The filter of claim 21, wherein the cells are arranged in a plurality of rings of neighboring cells, each ring being progressively more distant from the distal end and having cells that are larger than the cells of the ring next closest the distal end.

26. The filter of claim 25, wherein the cells of a first ring nearest to the distal end and the cells of a second ring farthest from the distal end each include one crossing region wherein the strands are slidably movable relative to each other, and wherein the cells of a third ring between the first and second

rings each include at least two crossing regions wherein the strands are slidably movable relative to each other.

27. The filter of claim 25, wherein each ring comprises at least six cells.

28. The filter of claim 21, wherein the paths of the strands that diverge from the twisted groups are substantially straight.

29. The filter of claim 21, wherein the paths of the strands that diverge from each of the twisted groups spiral in different directions.

30. A filter sized and constructed to be passed through the vasculature of a patient in a compressed condition and to be anchored in an expanded condition against an inner wall surface of a blood vessel for capturing blood clots in a blood stream passing therethrough, said filter including a filter portion that is substantially conical-shaped in the expanded condition, an apical distal end and an open proximal end, the filter portion comprising strands that extend from an open proximal end of the filter portion to an apical distal end, pairs of the strands forming twisted pairs that converge at the apical distal end, each of the strands forming each twisted pair diverging from the twisted pair near the apical distal end and extending therefrom in an approximately straight path that crosses a strand from a neighboring twisted pair, each strand being joined to another strand at the open proximal end, the crossing strands being relatively slidable at regions where they cross, in the expanded condition the crossing strands and the twisted pairs defining a plurality of four-sided, open cells, the cells being arranged in coaxial rings, the cells of each ring being progressively larger with distance from the apical distal end, the cells of a first ring nearest to the apical distal end and the cells of a second ring nearest the open proximal end each including only one of the crossing regions of relatively slidable strands, and the cells of an intermediate third ring each including two of the crossing regions of relatively slidable strands.

31. The filter as in any one of claims 3, 13, 18, 19 or 30, wherein the strands are formed from a member of the group consisting of nitinol, a temperature-sensitive shape memory material having a transition temperature around body temperature, a plastically deformable material, and an elastic material having a core formed from a radiopaque material.

32. The filter as in any one of claims 3, 13, 18, 19 or 30, wherein the strands form a woven pattern such that the strands are slidably movable relative to each other at their crossing regions.

33. The filter as in any one of claims 13, 18, 19 or 30, comprising an anchoring portion supporting the open proximal end of the filter portion, the anchoring portion comprising a self-expansible, substantially cylindrical-shaped body axially aligned with the filter portion, formed of a resilient material that urges the self-expansible body to radially expand and apply anchoring radial force against the inner wall surface of the blood vessel.

34. The filter as in either claim 1 or 12, wherein said self-expanding anchoring portion comprises a ring of neighboring cells.

35. The filter of claim 34, wherein the cells of said anchoring portion are self-expanding.

36. The filter of claim 34, wherein the neighboring cells of the anchoring portion are fixedly coupled together at respective areas of contact.

37. The filter of claim 34, the cells of said anchoring portion are formed from one or more resilient elongated strands.

38. The filter of claim 34, when the cylindrical body is in a compressed condition said cells of the anchoring portion are elongated in the axial direction.

39. The filter of claim 33, wherein one or more hooks are fixedly coupled to said anchoring portion, the one or more hooks being formed from compliant material having an original shape that bends under a stress and that returns to its original shape when the stress is removed, said one or more hooks respectively projecting from said anchoring portion at an acute angle with respect to the axial direction for engagement with a vessel wall, said one or more hooks further being deflectable toward said anchoring portion for achieving a low-profile.

40. The filter of claim 39, wherein said one or more hooks are formed from nitinol.

41. The filter of claim 39, wherein said one or more hooks preferentially bend toward and away from said vessel wall engaging portion.

42. The filter of claim 39, wherein said one or more hooks are formed from flat nitinol wire having a width dimension and having a thickness dimension substantially smaller than said width dimension for achieving preferential bending, said flat nitinol wire being oriented so that the thickness dimension of said flat nitinol wire coincides with a radial direction of the anchoring portion.

43. The filter of claim 34, wherein the strands extend beyond the open proximal end to form the body of the anchor portion.

44. The filter as in any one of claims 1, 12, 13, 18, 19, or 30, wherein said filter is coated with a drug for beneficial physiological effect.

45. The filter of claim 44, wherein the drug improves in vivo capability.

* * * * *

EXHIBIT 3

United States Patent [19]

Dormia

[11] **4,347,846**

[45] **Sep. 7, 1982**

[54] **SURGICAL EXTRACTOR**

[75] Inventor: **Enrico Dormia, Lecco, Italy**

[73] Assignee: **Porges, Paris, France**

[21] Appl. No.: **196,866**

[22] Filed: **Oct. 14, 1980**

[30] **Foreign Application Priority Data**

Dec. 7, 1979 [IT] Italy 27940 A/79

[51] **Int. Cl.**³ **A61B 17/00**

[52] **U.S. Cl.** **128/328**

[58] **Field of Search** 128/328, 345, 356

[56] **References Cited**

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Primary Examiner—Michael H. Thaler

Attorney, Agent, or Firm—Merriam, Marshall & Bicknell

[57] **ABSTRACT**

The present invention relates to a surgical extractor for removing foreign bodies from natural passages, of the type constituted by a flexible tube adapted to penetrate in the natural passages where the body to be extracted is located, the distal end of the tube comprising a cage or basket formed by steel wires which are retractable inside the tube in the positioning phase and adapted to be opened out for imprisoning the body to be extracted, expansion being ensured by maneuvering a steel wire housed in said tube and adapted to be maneuvered from the outside, wherein the retractable cage is formed by a plurality of flexible metal wires, for example steel wires, disposed in a helical path, certain of the wires following a helix in clockwise direction, while other wires, in equal number, follow a helix in anti-clockwise direction.

2 Claims, 5 Drawing Figures

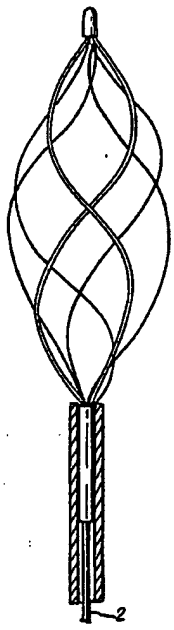


Fig: 1

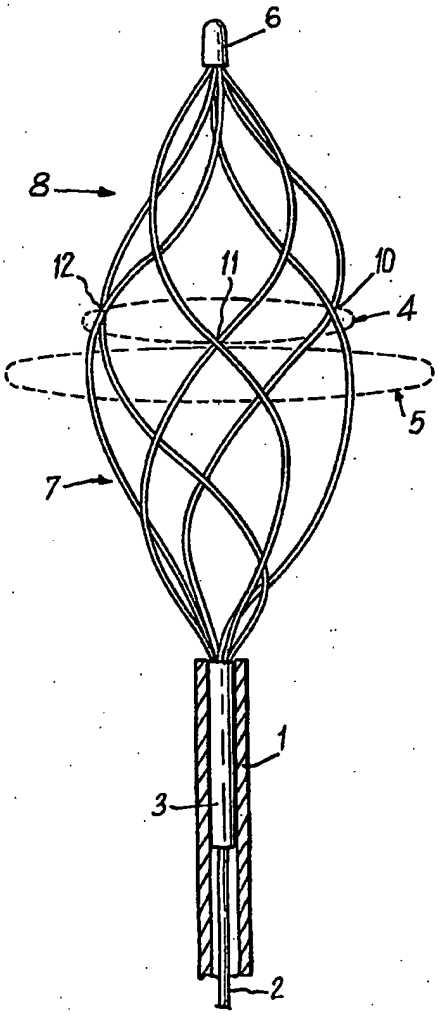


Fig: 2

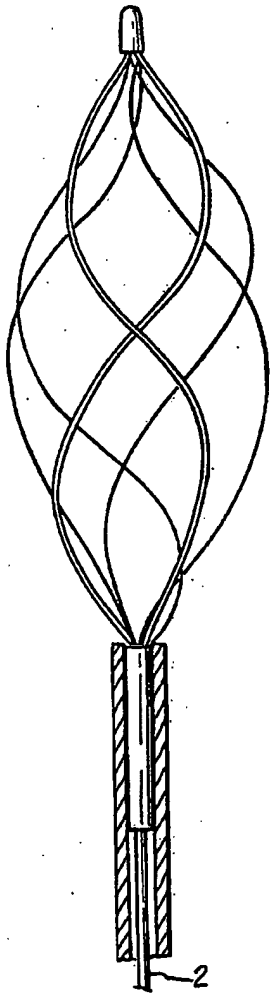


Fig:3

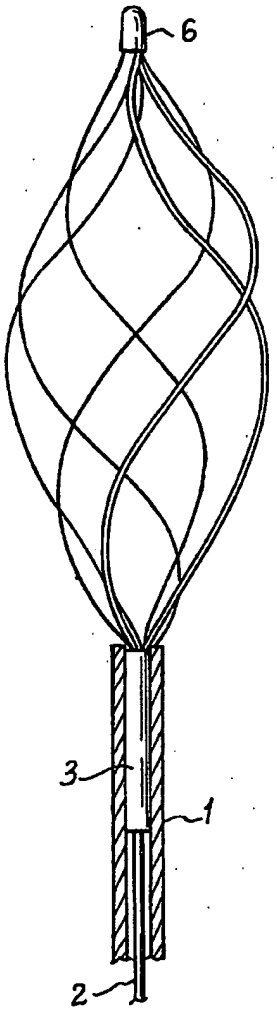


Fig:4

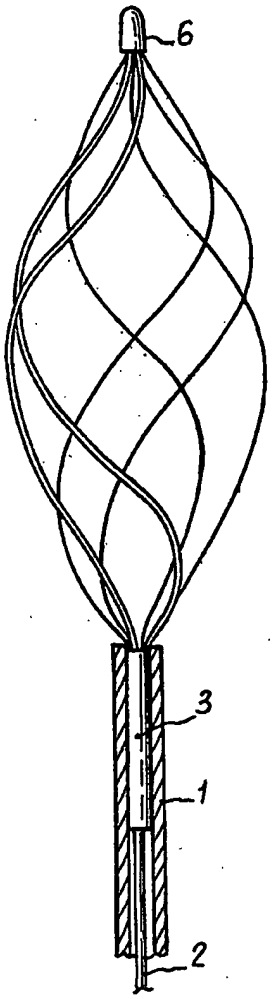
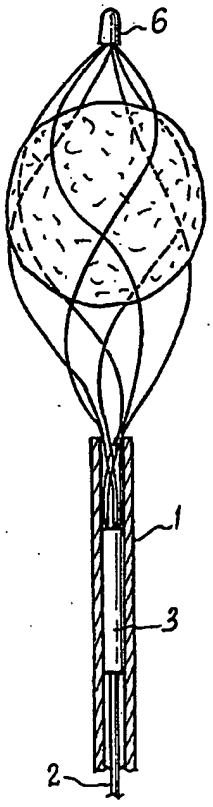


Fig:5



SURGICAL EXTRACTOR

The present invention relates to a device for extracting foreign bodies found in natural passages in the body, such as in the urinary tract, bile duct, blood vessels . . .

Devices are known which are used in particular in urology, for example for extracting a calculus from the ureter.

French Patent No. 1 197 808 in particular describes an instrument for making an extraction of this type; this instrument is constituted by a flexible tubular guide adapted to penetrate along the natural passages up to the spot where the body to be extracted is located; the tube contains a wire, for example made of steel, for controlling the manoeuvre, at the distal end of the tube, of a basket-like element formed by flexible wires, for example by an assembly of steel wires; this basket may retract inside the tube (for penetration of the latter in the natural passages) and it may open out, due to the manoeuvre of the steel wire, to imprison the body, for example the calculus; retraction of the basket will ensure total imprisonment of the calculus and retraction of the tube will enable the whole to be removed with the calculus imprisoned in the basket.

Various forms of basket or cage are known for ensuring greater efficiency, i.e. ensuring on the one hand manoeuvre of the basket when it passes from the retracted position to expanded position by opening out the wires constituting the bars of the cage adapted to imprison the body, then holding of the latter when the instrument is being withdrawn.

It will be seen that the cage or basket shapes must ensure a trap effect, i.e. facilitated passage of the body, for example a calculus or clot, inside the cage but then prevent escape thereof when it is in place in the cage and evacuated with the withdrawal of the instrument.

The shapes of wires forming the bars of the basket or cage as heretofore known, do not satisfy this double imperative.

In fact, in the shapes given to the wire constituting the bars of this retractable cage, the wires, in expanded position, follow parallel paths.

When these wires follow a helical path, a generally more enveloping shape is obtained; however, due to the spacing of the bars, small-sized bodies in particular escape between two adjacent bars, during the retraction manoeuvre.

It is an object of the present invention to remedy this drawback by providing an extractor of which the cage has the double advantage of facilitating penetration of the body during the imprisonment phase, whilst holding and blocking the body when the latter is held and present in the cage.

To this end, the invention relates to a surgical extractor for removing foreign bodies along the natural passages, of the type constituted by a flexible tube adapted to penetrate into the natural passages where the body to be extracted is located, the distal end of the tube comprising a cage composed of steel wires which are retractable inside the tube in the positioning phase and capable of being opened out to imprison the body to be extracted, the expansion being ensured by manoeuvring a steel wire housed in said tube and adapted to be manoeuvred from the outside, the extractor being characterised in that the retractable cage is formed by a plurality of flexible metal wires, for example steel wires, disposed in a helical path, whilst other wires, in equal number, follow a helix in anticlockwise direction.

A cage is thus produced whose wires intersect in pairs.

The points of intersections constitute zones where the body will be definitely imprisoned, being held firmly, without risk of escape between two parallel wires (as in the prior known extractors).

According to a prefered embodiment of the invention, the point of intersection of the two wires, clockwise and anti-clockwise respectively, is located beyond the equatorial plane of the cage (in the form of a spindle).

According to this feature, it will be understood that as the zones to intersection are located towards the distal end of the cage, the latter is of dissymmetrical structure.

The low part of the cage (located near the tube) comprises wires which are spaced apart without intersecting; it is precisely through this zone that the body penetrates inside the cage.

In fact, it is known that, when using an extractor of this type, the end of the tube is brought in the immediate vicinity of the calculus or body to be extracted; and the cage opens out beyond the calculus or body so that the latter is substantially at the level of the lower part of the cage where there is no intersection of wires and where, consequently, the wires forming bars are adapted to the penetration of the body and can easily envelop it.

On the contrary, in the upper or terminal part of the cage are found the zones of intersection of two wires, this zone forming a barrier, due to the intersection of the wires, imprisoning the body.

The extraction manoeuvre begins by a contracting of the cage, which is partially retracted inside the tube, so that the low part of the cage (or "open" part) will be retracted inside the tube and placed in inactive position; the calculus or body to be extracted is then held in the upper part of the cage which precisely constitutes the "closed" part due to the wire intersections.

Under these conditions, it will be understood that the body may penetrate in an extractor according to the invention as easily as in a conventional extractor, but, once in the cage, the latter prevents any accidental escape.

The present invention therefore improves efficiency in the extraction manoeuvre and has proved particularly effective, during the tests and experiments which have been carried out, in difficult cases such as sand in the ureter, microlithiasis in the bile duct, and obstruction of the blood vessels.

In addition, the arrangement of the wires under the conditions described hereinabove avoids during extraction, any danger of twisting of the passage in which the extractor is inserted, contrary to what may occur with the cage composed of parallel wires.

By using the arrangement provided in the present invention, wires of vary small dimensions, of up to 2/10th millimeter, may be used.

During the manoeuvre for retracting the extractor, a greater stability of the whole is therefore obtained, which allows th doctor to work under more reliable and more efficient conditions than before.

The invention will be more readily understood on reading the following description with reference to the accompanying drawings, in which:

FIG. 1 shows a view in perspective of a cage disposed at the end of an extractor according to the invention.

FIGS. 2, 3 and 4 successively show, to clarify the invention, the three pairs of wires (each formed by a clockwise helical wire and by an anti-clockwise helical wire) constituting the extractor according to the invention.

FIG. 5 shows a view of the extractor according to FIG. 1, after imprisonment of a calculus and after partial retraction of the cage.

Referring not to the drawings, the extractor is composed in conventional manner of a flexible tube 1 in which penetrates the manoeuvring wire, for example the steel wire 2 which acts on the terminal cylinder 3 sliding at the end of the tube 1.

The wires which form the extraction cage according to the invention emerge from the cylinder 3.

It will be seen that, depending on the manoeuvre of the sliding cylinder 3, controlled by the wire 2, the wires of the cage may retract inside the end of the tube 1 and subsequently open out, inside the passage where the calculus is located, to imprison the latter.

In the example described here, the cage is composed of six wires, viz, three wires disposed helically in clockwise direction, and three other wires disposed helically in anti-closkwise direction.

To clarify the drawings, FIGS. 2, 3 and 4 each successively show pairs of wires, each pair comprising a clockwise wire and an anti-clockwise wire.

These wires (belonging to the same pair) intersect at a level represented by circle 4 (FIG. 1).

According to a feature of the invention, the transverse plane 4 corresponding to the level of the intersections of the wires is located above and towards the distal end 6 with respect to the plane 5 which corresponds to the equatorial plane of the spindle formed by the cage.

It is thus seen that, in the lower zone 7, the wires do not intersect and, under these conditions, they form an open structure allowing the calculus to penetrate easily.

On the contrary, in the upper part 8, the zones of intersection 4 form a closed structure which enables the calculus to be firmly imprisoned.

FIG. 5 shows the phase of imprisonment of the calculus; the lower part of the cage is partially closed by penetration in the tube and the calculus is thus forced back towards the upperpart of the cage, i.e. the closed part where the intersections 10,11 and 11' of the wires (FIG. 1) will imprison the calculus firmly.

What is claimed is:

1. In a surgical extractor for removing bodies from natural passages, of the type comprising a flexible tube adapted to be inserted in a natural passage where the body to be extracted is located, the distal end of the tube having a retractable cage formed by flexible metal wires which are retractable inside the tube for positioning the tube in the passage and extendable for trapping the body to be extracted,

the improvement wherein the retractable cage is formed by a plurality of flexible metal wires arranged in pairs and disposed in helical paths, one wire of each pair being spiralled in clockwise direction and the other in anti-clockwise direction,

the wires of each pair intersecting at a single point between the ends thereof,

the spacing between wires in said cage being sufficient to permit the passage of said body into the interior of said cage.

2. An extractor in accordance with claim 1 wherein said point of intersection lies substantially in a plane located between the equitorial plane of the cage and the distal end thereof, whereby the cage comprises a relatively open proximal face in which the wires are relatively widely spaced, allowing free passage for the body to be trapped, and a relatively closed distal face in which the intersecting wires impede passage therethrough of the trapped body.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 4,347,846

DATED : September 7, 1982

INVENTOR(S) : ENRICO DORMIA

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Col. 1, line 35, "facilitated" should be --facilitate--.

Col. 2, line 1, after "path", insert the following

--certain of the wires following a helix in clockwise direction--.

Signed and Sealed this

Fifteenth Day of *February 1983*

[SEAL]

Attest:

GERALD J. MOSSINGHOFF

Attesting Officer

Commissioner of Patents and Trademarks

EXHIBIT 4

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Synonyms

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attacapa
attacapan
attacca
attaccaed

attach - 8 dictionary results

at·tach [*uh*-**tach**] Show IPA

–verb (used with object)

1. to fasten or affix; join; connect: *to attach a photograph to an application with a staple.*
2. to join in action or function; make part of: *to attach oneself to a group.*
3. *Military.* to place on temporary duty with or in assistance to a military unit.
4. to include as a quality or condition of something: *One proviso is attached to this legacy.*
5. to assign or attribute: *to attach significance to a gesture.*
6. to bind by ties of affection or regard: *You always attach yourself to people who end up hurting you.*
7. *Law.* to take (persons or property) by legal authority.
8. *Obsolete.* to lay hold of; seize.

–verb (used without object)

9. to adhere; pertain; belong (usually fol. by *to* or *upon*): *No blame attaches to him.*

Origin:
1300–50; ME *atachen* < AF *atacher* to seize, OF *atachier* to fasten, alter. of *estachier* to fasten with or to a stake, equiv. to *estach*(e) (< Gmc **stakka* STAKE) + *-ier* inf. suffix

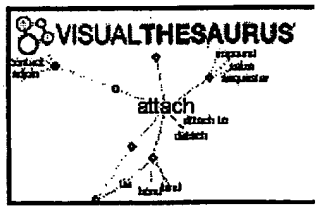
attaccaing
attach
attach to
attach'e
attachable
attache
attache case

Related forms:
at□tach□a□ble, adjective
at□tach□er, noun

Synonyms:
1. subjoin, append, add, annex.

Antonyms:
1. detach.

NEW Related Words for : **attach**
bind, bond, tie, confiscate, impound
View more related words »



Explore the Visual Thesaurus

at·tach (□-tăch') ?
v. **at·tached, at·tach·ing, at·tach·es**

v. *tr.*
1. To fasten, secure, or join: *attached the wires to the post.*
2. To connect as an adjunct or associated condition or part: *Many major issues are attached to this legislation.*
3. To affix or append; add: *attached several riders to the document.*
4. To ascribe or assign: *attached no significance to the threat.*
5. To bind by emotional ties, as of affection or loyalty: *I am attached to my family.*
6. To assign (personnel) to a military unit on a temporary basis.
7. *Law* To seize (persons or property) by legal writ.

v. *intr.*
To adhere, belong, or relate: *Very little prestige attaches to this position.*

[Middle English attachen, from Old French attachier, alteration of estachier, from estache, *stake, of Germanic origin.*]
at·tach'a·ble *adj.*, **at·tach'er** *n.*

Attach

At*tach"\, v. t. [imp. & p. p. Attached; p. pr. & vb. n. Attaching.] [OF. atachier, F. attacher, to tie or fasten: cf. Celt. tac, tach, nail, E. tack a small nail, tack to fasten. Cf. Attack, and see Tack.]

1. To bind, fasten, tie, or connect; to make fast or join; as, to attach one thing to another by a string, by glue, or the like.

The shoulder blade is . . . attached only to the muscles. --Paley.

A huge stone to which the cable was attached. --Macaulay.

2. To connect; to place so as to belong; to assign by authority; to appoint; as, an officer is attached to a certain regiment, company, or ship.

3. To win the heart of; to connect by ties of love or self-interest; to attract; to fasten or bind by moral influence; -- with to; as, attached to a friend; attaching others to us by wealth or flattery.

Incapable of attaching a sensible man. --Miss Austen.

God . . . by various ties attaches man to man. --Cowper.

4. To connect, in a figurative sense; to ascribe or attribute; to affix; -- with to; as, to attach great importance to a particular circumstance

Top this treasure a curse is attached. --Bayard Taylor.

5. To take, seize, or lay hold of. [Obs.] --Shak.

6. To take by legal authority: (a) To arrest by writ, and bring before a court, as to answer for a debt, or a contempt; -- applied to a taking of the person by a civil process; being now rarely used for the arrest of a criminal. (b) To seize or take (goods or real estate) by virtue of a writ or precept to hold the same to satisfy a judgment which may be rendered in the suit. See Attachment, 4.

The earl marshal attached Gloucester for high treason. --Miss Yonge.

Attached column (Arch.), a column engaged in a wall, so that only a part of its circumference projects from it.

Syn: To affix; bind; tie; fasten; connect; conjoin; subjoin; annex; append; win; gain over; conciliate.

Attach

At*tach"\, v. i. 1. To adhere; to be attached.

The great interest which attaches to the mere knowledge of these facts cannot be doubted. --Brougham.

2. To come into legal operation in connection with anything; to vest; as, dower will attach. --Cooley.

Attach

At*tach"\, n. An attachment. [Obs.] --Pope.

Webster's Revised Unabridged Dictionary, © 1996, 1998 MICRA, Inc.
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NEW Language Translation for : **attach**
Spanish: **atar, sujetar, adjuntar,** German: **befestigen,**
Japanese: **付ける**
More Translations »

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attach
1330, "to take or seize (property or goods) by law," a legal term, from O.Fr. estachier "to attach" (Fr. attacher, It. attaccare), perhaps from a- "to" + Frank. *stakon "a post, stake" or a similar Gmc. word (see stake (n.)). Meaning "to fasten, affix, connect" is first attested 1802, from French. Attachment "affection, devotion" is from 1704.

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Main Entry: **at·tach**
Function: *verb*
Etymology: Anglo-French *attacher* to lodge (an action in court), seize (a person or property) by legal authority, from Old French *atachier* tc fasten, fix, alteration of *estachier*, from *estache* stake
transitive verb **1 :** to obtain a court order against (property of another person) that directs an officer of the court (as a sheriff) to seize or take control of the property —compare GARNISH, LEVY
NOTE: A plaintiff may attach a defendant's property as a way of obtaining jurisdiction for the purpose of bringing a lawsuit or to prevent the defendant from getting rid of property that may be needed to pay a judgment to the plaintiff.
2 : to join or make a part of attach*ed* to the suit —Rosalind Resnick> **3 :** to create a security interest in (property) and so acquire the right to foreclose on or otherwise deal with property for payment of a debt and to exercise one's rights in the property against third parties — see also *security interest* at INTEREST 1 —compare PERFECT
intransitive verb **:** to become effective: as **a :** to come into existence as a security interest attach*es*> **b :** to become operative esp. as a right attach*es* only at or after the initiation of adversary judicial proceedings —*United States v. Gouveia*, 467 U.S. 180 (1984)> —see also JEOPARDY **—at·tach·able** *adjective* **—at·tach·ment** *noun*

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attach

see no strings attached.

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